Government of Jamaica

The Biosafety Policy for Jamaica

July 2021

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Message

As we journey on the road to prosperity, we must be cognizant of the fact that economic advances are underpinned by science and technology and a healthy natural environment. This is captured in our Vision 2030 Jamaica: National Development Plan under National Outcomes 11 - A Technologically-enabled Society; and 13 - Sustainable Management and Use of Environmental and Natural Resources. In this Biosafety Policy for Jamaica, these two areas are not mutually exclusive.

While biotechnology is not new, recent advances raise a host of environmental, social and health issues. As such, having recognized both the importance of modern biotechnology in advancing as a country, the inherent risks to our natural environment and health must be paramount in our considerations for its application. This Policy seeks to strike this balance by setting out the framework whereby Jamaica will be able to meet not only its international obligations, specifically those set out in the Cartagena Protocol on Biosafety to Convention on Biological Diversity which Jamaica is a Party, but also its peculiar needs and requirements.

The Vision of the Policy is "Jamaica has an enabling environment for the safe development and utilization of modern biotechnology, resulting in minimal risks to human health and biodiversity while providing benefits to health, agriculture and industry." Its goal is "To provide a safe and enabling environment for the development, transboundary movement, handling and use of living modified organisms, while managing any potential risks to human health and biodiversity." This Vision and Goal are underpinned by a number of principles and values, chief of which is the precautionary approach, that is, where a potential threat to our environment or human health is identified, lack of scientific certainty should not be used as a reason for not taking action to prevent environmental degradation or harm to human health.

The implementation of this Policy will result in:

- the effective regulation of the transboundary movement (import and export) of living modified organisms (LMOs) in keeping with the relevant international rules and standards as well as the Cartagena Protocol on Biosafety;

- the mitigation of the possible adverse effects of LMOs on human health and biodiversity;

- the promotion of the development and utilization of modern biotechnology at the national level that may provide financial benefits to the relevant sectors taking into account issues of biosafety;

- the establishment of standards for the safe handling, storage, transport and use of LMOs, including packaging, labelling, documentation, disposal and contingency procedures, in keeping with international labelling standards;

- increased public education and awareness and information sharing on biosafety to facilitate effective implementation of the national biosafety regime;

- increased capacity of the relevant national institutions to implement and monitor a national framework for biosafety.

As a Party to the Cartagena Protocol on Biosafety, the Government is required is to provide an enabling environment to allow for advancements in modern biotechnology. This includes the institution of measures and mechanisms to facilitate the effective monitoring and regulation of the sector in an effort to mitigate any potential adverse effects. This Biosafety Policy for Jamaica is one key step in this regard. This Policy will allow for, *inter alia*, the strengthening of the governance framework related to biosafety, including the: (i) promulgation of national biosafety legislation as well as the re-establishment of the multi-stakeholder National Biosafety Committee, (ii) promotion of risk assessments and risk management of LMOs, (iii) strengthening of institutional capacities in biosafety, particularly within the public sector, (iv) increased public education and awareness, (v) comprehensive research programme, and (vi) improved public participation in the decision-making process to allow for informed decisions and actions with respect to biosafety matters.

As we all work together to make Jamaica the place of choice to live, work, raise families, and do business, we must ensure biosafety is integrated into all sectors. I encourage all Jamaicans to learn all we can about this issue and to do our part in the implementation of this National Policy on Biosafety.

Honourable Pearnel Charles, Jr., MP
Minister of Housing, Urban Renewal, Environment and Climate Change
July 2021

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List of Acronyms

AIA	Advance Informed Agreement
BCH	Biosafety Clearing-House
BSJ	Bureau of Standards Jamaica
CAC	Consumer Affairs Commission Jamaica
CARICOM	Caribbean Community
CSME	CARICOM Single Market and Economy
FAO	Food and Agriculture Organization
FFP	Food or Feed, or for Processing
GATT	General Agreement on Tariffs and Trade
GEF	Global Environment Facility
GEO	Genetically Engineered Organism
GM	Genetically Modified
GMO	Genetically Modified Organism
IOJ	Institute of Jamaica
IPPC	International Plant Protection Convention
JACRA	Jamaica Agricultural Commodities Regulatory Authority
JADF	Jamaica Agricultural Development Foundation
JCA	Jamaica Customs Agency
LMO	Living Modified Organism
MRA	Ministry with Responsibility for Agriculture
MRE	Ministry with Responsibility for the Environment
MTF	Medium Term Socio-Economic Policy Framework
MSET	Ministry of Science, Energy and Technology
NBF	National Biosafety Framework
NBC	National Biosafety Committee
NEPA	National Environment and Planning Agency
NCST	National Commission on Science and Technology
NRCA	Natural Resources Conservation Authority
OIE	World Organization for Animal Health[1]
RADA	Rural Agriculture Development Authority
SPS	Sanitary and Phytosanitary Measures
SRC	Scientific Research Council
TBT	Technical Barriers to Trade
TRIPS	Trade-Related Aspects of Intellectual Property Rights
UNE	United Nations Environment Programme
UWI	University of the West Indies

[1] The organization was renamed in 2003 but retained its historical acronym "OIE".

VSD	Veterinary Services Division
WHO	World Health Organization
WTO	World Trade Organization

Executive Summary

The Cartagena Protocol on Biosafety, a supplementary agreement to the Convention on Biological Diversity, was adopted on 29 January 2000 and came into force on 11 September 2003. The Protocol aims to ***"contribute to ensuring an adequate level of protection in the safe transfer, handling and use of living modified organisms resulting from modern biotechnology that may have adverse effects on the conservation and sustainable use of biological diversity, taking also into account the risks to human health, and specifically focusing on transboundary movements through planned or accidental import/export."*** Jamaica signed the Protocol in June 2001 and became a Party on 24 December 2012.

The National Biosafety Policy for Jamaica is the product of deliberations by a range of state and non-state actors, many of which were represented on the National Biosafety Committee, as well as, consultations with stakeholders. It sets out objectives, strategies and implementation procedures for a number of state-led activities, which together create the framework for a national biosafety regime. It addresses the safe use, transportation, containment, storage and handling of living modified organisms (LMOs) – including requirements for transboundary movement and provides a framework for supporting research and public education on modern biotechnology.

Purpose of the Policy

The Policy is designed to meet international obligations, specifically those set out in the Cartagena Protocol on Biosafety, and the peculiar needs and requirements of Jamaica as it seeks to benefit from the advantages of modern biotechnology, while reducing risks to biodiversity, health and the environment to the extent possible.

Policy Vision

Jamaica has an enabling environment for the safe development and utilization of modern biotechnology, resulting in minimal risks to human health and biodiversity while providing benefits to economic sectors, including health, agriculture and industry.

Policy Goals

The goals of the Biosafety Policy for Jamaica are:

1. To manage the risks to human health, agriculture and biodiversity from the development, transboundary movement, handling and use of living modified organisms;
2. To facilitate the development of a national modern biotechnology sector in a safe and regulated environment;

Policy Objectives

The objectives of the National Biosafety Policy are to:

1. ensure the effective regulation of the transboundary movement (import and export) of LMOs is in keeping with the relevant international rules and standards as well as the tenets of the Cartagena Protocol on Biosafety;

2. ensure that the possible adverse effects of LMOs on human health and biodiversity are effectively mitigated and managed;

3. promote the development and utilization of modern biotechnology at the national level that may provide financial benefits to the relevant sectors taking into account issues of biosafety;

4. establish national standards, in keeping with international standards, for the safe handling, storage, transport, detection, identification and use of LMOs, including packaging, labelling, documentation, disposal and contingency procedures;

5. increase public education and awareness and information sharing on biosafety to facilitate effective implementation of the national biosafety regime;

6. increase the capacity of the relevant national institutions to implement and monitor a national framework for biosafety;

LMOs which are pharmaceuticals for humans are not addressed in this Policy. It should be noted however, that this category of LMOs is covered under the legislation and policies related to drugs under the mandate of the Ministry of Health.

This Policy is to be read and implemented in conjunction with a range of complementary national laws and policies[2], including the draft National Biotechnology Strategy (2005) which outlines the options available for utilizing biotechnology as well as the draft Biotechnology Policy (2006) which articulates the regulatory framework for the biotechnology industry. A new Science, Technology and Innovation Policy is also being developed by the Ministry of Science, Energy and Technology.

The provisions of the Biosafety Policy will be implemented through legislation, including biosafety legislation which is to be developed as a priority of the Government. Through periodic review, by the Ministries with responsibility for the environment and agriculture

[2] A summary of the main laws is included in Appendix 1.

respectively, the Policy will be revised as necessary to take into account new developments regarding modern biotechnology.

In addition to the inputs and expertise of local stakeholders, the preparation of this Policy was facilitated through financial support from the Global Environment Facility and the United Nations Environment Programme.

1. INTRODUCTION

1.1 The term `biotechnology' refers to any technological application that uses biological systems, living organisms, or derivatives thereof, to make or modify products or processes for a specific use. Biotechnology, in the form of traditional fermentation techniques, has been used for decades to make bread, cheese or beer. It has also been the basis of traditional animal and plant breeding techniques, such as hybridization and the selection of plants and animals with specific characteristics to create, for example, crops which produce higher yields of grain.[3]

1.2 Modern biotechnology is defined under the Cartagena Protocol on Biosafety as the application of:

a) In vitro nucleic acid techniques, including recombinant deoxyribonucleic acid (DNA) and direct injection of nucleic acid into cells or organelles, or
b) Fusion of cells beyond the taxonomic family, that overcome natural physiological reproductive or recombination barriers and that are not techniques used in traditional breeding and selection;

One example of modern biotechnology is genetic engineering to create living modified organisms/genetically engineered organisms (LMOs/GEOs) through "transgenic technology" involving the insertion or deletion of genes.[4]

1.3 Through modern biotechnology research, new genetically modified plant or animal life forms are continually being developed for use in agriculture, horticulture, the food industry, medical research, the pharmaceutical industry, the production of biofuels and other areas. While these living modified organisms (LMOs) have the potential to advance human development, the risks attendant to their use must be identified and carefully managed. These risks include possible threats to biodiversity, to human, plant and animal health as well as the socio-economic consequences of introducing LMOs and their derivatives into the environment or the marketplace. The process of managing these risks is referred to as biosafety.

[3] https://www.cbd.int/doc/legal/cartagena-protocol-en.pdf

[4] UNEP/GRID-Arendal. Biotechnology and modern biotechnology defined. UNEP/GRID-Arendal Maps and Graphics Library. 2008. Available at: http://maps.grida.no/go/graphic/biotechnology-and-modern-biotechnology-defined. Accessed June 10, 2009.

2. SITUATIONAL ANALYSIS

2.1 Historical Context

2.1.1 Biosafety issues were first introduced into the Jamaican policy agenda in 1997 when the Jamaica Agricultural Development Foundation (JADF) requested permission from the then Plant Quarantine Division[5] under the Ministry with portfolio responsibility for agriculture for the importation of plants that were genetically engineered by a Jamaican studying in the United States. The plant was a transgenic Solo variety papaya on which research was to be conducted at the Biotechnology Centre at the University of the West Indies, Mona. This request highlighted the fact that there was no national legislative or regulatory mechanism in place for the processing of such applications.

2.1.2 As a precursor to the initiation of local transgenic research trials, the National Biosafety Committee (NBC) was formed as a multi-sectoral team, comprising both state and non-state actors, with secretariat support provided by the National Commission on Science and Technology (NCST). The NBC was given a statutory mandate under the Plants (Importation) Control Regulations, 1997 to approve applications for the importation of plants, seeds, cuttings or slips and make recommendations accordingly to the Plant Quarantine Division for the grant of the import permit. These regulations were amended in 2005, including amendments to the section on GMOs. In determining whether to grant approval of an application, the NBC shall consider the applicant's ability to enforce adequate procedures and safeguards to ensure that no contamination by or release of the plant, seed, cutting or slip which is detrimental to the health or safety of any human, animal, or other living organism will occur at the port of entry or otherwise in the Island.

2.1.3 The initiatives of the aforementioned NBC included, *inter alia*:

- development of draft Guidelines for the Release of LMOs into the Environment;
- implementation of a public education programme on biosafety from 2001 to 2002;
- establishment of a National Biosafety Clearing-House hosted by the Institute of Jamaica (IOJ);
- monitoring of field trials on transgenic papaya; and
- provision of guidance in the development of a National Biosafety Policy.

[5] The Plant Quarantine Division has been renamed the Plant Quarantine/Produce Inspection Branch.

2.1.4 In 2002, the Government received financial support from the Global Environment Facility and the United Nations Environment Programme under the Development of National Biosafety Frameworks Project to develop, *inter alia*, a National Biosafety Policy and a National Biosafety Act.

2.1.5 Jamaica became a Party to the Convention on Biological Diversity on April 6, 1995, signed the Cartagena Protocol on Biosafety on June 4, 2001 and later ratified the instrument on December 24, 2012. The Protocol recognizes the potential benefits of modern biotechnology for human well-being when developed and used with adequate safety measures for the environment and human health, while seeking to ensure the safe use, handling, transport, transfer and release of LMOs with a particular focus on transboundary movement of living modified organisms.

2.2 Regional Context

2.2.1 The agenda for biosafety within the Caribbean Community (CARICOM) is being advanced within the context of the *Revised Treaty of Chaguaramas Establishing The Caribbean Community Including The CARICOM Single Market And Economy*. With the establishment of the CARICOM Single Market and Economy (CSME) a legal foundation has been provided for the movement of goods, services, capital and skills among Member States. As a result of the CSME, there is need to harmonize the national biosafety frameworks among CARICOM Member States. In this regard, a Working Group on Biosafety and Biotechnology was established by the Council on Trade and Economic Development of CARICOM with a mandate to develop a regional Biotechnology/ Biosafety Policy and Strategy. To date, this regional policy/strategy has not been finalized.

2.2.2 Subsequent to the regional project mentioned in 2.1.4, a second UNEP/GEF regional project for the twelve (12) CARICOM countries which were Parties to the Cartagena Protocol, not including Jamaica, was approved in 2011[6] "… to implement effective, operable, transparent and sustainable National Biosafety Frameworks (NBF) which addresses national and regional needs, deliver global benefits and are compliant with the Cartagena Protocol on Biosafety." The Project addressed the establishment of national legal frameworks for biosafety/biotechnology, capacity building including the carrying out of risk assessments and management and the institutionalization of national and regional mechanisms to provide access to biosafety information in order

[6] It is important to note that Jamaica did not participate in this project as the country was not yet a Party to the Biosafety Protocol.

to promote transparency, raise public awareness and facilitate biosafety decision-making in the Caribbean. The development of a Regional Biosafety Clearing-House node was also an objective of the Project.

2.2.3 The *Revised Final Draft CARICOM Regional Biotechnology Biosafety Policy & Strategy (2009)* specifies the comparative advantage of the region related to biosafety, biotechnology, science and technology and agriculture. These areas include:

- Agriculture and food: for example, development of diagnostic kits for plant diseases; development of specific biosensors; use of microbial technologies to develop biopesticides and biofertilisers; production of natural products from medicinal plants; production of transgenic crops with improved agronomic traits; and development of new ornamental plant varieties;
- Medicine and healthcare: for example, tropical diseases transmitted by insect vectors (dengue and malaria); health and wellness tourism;
- Industrial applications: for example, development of food and industrial enzymes; development of specific biosensors for agriculture, mining, bioremediation and waste management; use of biomass in the agricultural sector for the development of biopolymers;
- Environment and energy: for example, identification of microorganisms which can be used for waste management; development of biosensors for identification of water and mining pollutants; development of bioenergy sources; and
- Biodiversity management for new products: for example: characterization of genetic resources for purposes of conservation using molecular or other techniques; development of micropropagation protocols; identify and conserve fish stock and for development of aquaculture.

2.3 International Context

2.3.1 There are several international agreements that have an impact on global biosafety policy and are relevant to biosafety regulation at the national level, namely:

The Cartagena Protocol on Biosafety

2.3.2 Article 19 of the Convention on Biological Diversity requires Parties to the Convention to consider the need for and modalities of a protocol setting out appropriate procedures including, in particular, advance informed agreement, in the field of the safe transfer, handling and use of any living modified organisms and their products.

2.3.3 After six years of negotiations, the Cartagena Protocol on Biosafety was adopted on January 29, 2000 at an Extraordinary Conference of the Parties to the Convention on Biological Diversity and entered into force on 11 September 2003. Its main objective is ensuring an adequate level of protection in the safe transfer, handling and use of LMOs that may have adverse effects on the conservation and sustainable use of biological diversity, taking into account risks to human health and specifically focusing on transboundary movements.

2.3.4 Although the Protocol covers all LMOs, it primarily addresses two particular uses of LMOs, namely: (1) those to be intentionally introduced into the environment; and (2) those directly used for food, feed, or processing ("FFP"). For LMOs used for other purposes, such as LMOs used in the laboratory, the Protocol leaves regulation to the discretion of the individual country. The Protocol also does not cover products derived from LMOs, such as processed foods that contain ingredients derived from LMOs, and, human pharmaceuticals that are "addressed by other relevant international agreements or organizations".

2.3.5 The preamble to the Protocol states, *inter alia*, that trade and environmental agreements should be mutually supportive with a view to achieving sustainable development, that the Protocol shall not be interpreted as implying a change in the rights and obligations of a Party under any existing international agreement, but that these and other caveats stated in the preamble are not intended to subordinate the Protocol to other international agreements.

2.3.6 The Cartagena Protocol sets an enabling environment for regulating transboundary movements of LMOs by establishing a set of procedures that both exporting and importing countries should follow. This is referred to as the Advance Informed Agreement (AIA) procedure. The Protocol also underscores the applicability of the precautionary approach, which allows countries to take conservative, risk prevention measures in the absence of sufficient scientific data on the impact that an LMO may have on human health and or biodiversity. The AIA procedure is not required in the case of LMOs in transit, LMOs destined for contained use, and LMOs intended for direct use for FFP.

2.3.7 Jamaica's focal point to the Cartagena Protocol on Biosafety is the Environment and Risk Management Branch of the Ministry with responsibility for the environment.

The International Plant Protection Convention

2.3.8 This Convention sets a framework for protecting plant health by assessing and managing the risks to plants and pests, including risks associated with LMOs and invasive species. The International Plant Protection Convention (IPPC) allows governments to take action to prevent the introduction and spread of such pests, and can thus affect the transboundary movement of any LMO that could be considered a plant pest.

2.3.9 The IPPC established an open-ended working group on phytosanitary aspects of LMOs, biosafety and invasive species. The Working Group will develop standards for risk analysis as applied to environmental hazards.

2.3.10 Jamaica's contact point under the Convention is the Chief Plant Quarantine Officer and the Plant Quarantine/ Produce Inspection Branch is the National Plant Protection Organisation.

International Treaty on Plant Genetic Resources for Food and Agriculture (also known as the International Seed Treaty)

2.3.11 The aims of this treaty, which entered into force on 29 June 2004, are:

- recognition of the enormous contribution of farmers to the diversity of crops that feed the world;
- establishment of a global system to provide farmers, plant breeders and scientists with access to plant genetic materials; and
- to ensure that recipients share benefits they derive from the use of genetic materials with the countries of origin.

2.3.12 Jamaica acceded to this Treaty on 14 March 2006.

The World Trade Organization (WTO) Agreements

2.3.13 The original General Agreement on Tariffs and Trade (GATT 1947) was revised as part of the Uruguay Round and the revised text, GATT 1994, constitutes an integral part of the WTO. GATT 1994 is the umbrella agreement for trade in goods and covers the basic principles that form the foundation of the multilateral trading system. Its rules continue to apply where not superseded by a more specific WTO Agreement. Article XX gives Members the legal means to balance their trade obligations with non-trade objectives such as protection of health or the environment.

2.3.14 A number of agreements under the WTO contain provisions that are applicable to biosafety, including the following:

- Agreement on the Application of Sanitary and Phytosanitary Measures (SPS);
- Agreement on Technical Barriers to Trade (TBT); and
- Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS).

2.3.15 The most relevant WTO agreement related to biosafety is the SPS Agreement, the underlying objective of which is to ensure that member states do not use food safety, animal and plant health regulations as trade barriers in order to protect their domestic agricultural industries from competitive imports.

Agreement on Sanitary and Phytosanitary Measures (SPS)

2.3.16 The SPS Agreement covers all measures whose purpose is to protect (i) human or animal health from food-borne risks; (ii) human health from animal- or plant-carried diseases; (iii) animals and plants from pests or diseases; and (iv) the territory of a country from other damage caused by the entry or spread of pests, including invasive species. This protection applies whether a country has technical measures in place or not. The Agreement covers all plants and animals, including commercially important species, and includes fish, wild fauna and flora. The SPS Agreement permits States to impose measures necessary to protect human, animal or plant life or health.

2.3.17 The SPS Agreement recognizes the standards, guidelines and recommendations of three standard-setting organizations, that is, the World Organization for Animal Health, the Codex Alimentarius Commission and the International Plant Protection Commission (see below).

Agreement on Technical Barriers to Trade (TBT)

2.3.18 This Agreement aims to ensure that regulations, standards, testing and certification procedures do not create unnecessary obstacles to trade. However, the TBT Agreement recognizes the rights of Member States to adopt the standards they consider appropriate - for instance to protect human, animal or plant life or health, or the environment, or to meet other consumer interests.

TRIPS Agreement

2.3.19 The Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement) establishes global minimum standards for protecting and enforcing nearly all forms of intellectual property rights including those for patents.

Related International Organizations

2.3.20 In addition to the treaties outlined in 2.3.8 – 2.3.19 above, there are other global entities whose work impacts on biosafety issues. These include:

The Codex Alimentarius Commission

2.3.21 This Commission (established under the Food and Agriculture Organization (FAO) and the World Health Organization (WHO)) addresses food safety and consumer health. An ad hoc Intergovernmental Task Force on Foods Derived from Biotechnology was established to develop standards, guidelines or recommendations, as appropriate, for foods derived from modern biotechnology or traits introduced into foods by modern biotechnology, on the basis of scientific evidence, risk analysis and having regard, where appropriate, to other legitimate factors relevant to the health of consumers and the promotion of fair practices in the food trade. The Task Force completed its work in 2007.

2.3.22 The Task Force developed standards and guidelines for LMOs in food products, including the issues of labelling and consumer information as well as general principles for risk analysis for genetically modified (GM) foods, and specific guidance on risk assessment which have been adopted by the Codex Alimentarius Commission. They include:

- principles for the risk analysis of foods derived from modern biotechnology;
- guidelines for the conduct of food safety assessment of foods derived from recombinant-DNA plants; and
- guidelines for the conduct of food safety assessment of foods produced using recombinant-DNA micro-organisms.

2.3.24 In 2004, the BSJ established a National CODEX Committee in 2004 in response to the globalized shift for international standards for goods and agricultural produce. The Committee brings together the Ministries responsible for Commerce, Science and Technology; Agriculture; and Health.

The World Organization for Animal Health (OIE)[7]

2.3.24 The OIE addresses the international trade in animals, animal genetic material and animal products, and seeks to prevent the introduction of infectious agents and diseases in the course of such trade.

[7] In May 2003 the Office International des Epizooties (OIE) established in 1924 became the World Organization for Animal Health but kept its historical acronym OIE.

2.3.25 Some of the standards developed by the OIE address diseases that have human health and biosafety significance. These standards are approved by the OIE member countries and published in the OIE International Animal Health Code. The OIE also publishes the Manual of Standards for Diagnostic Tests and Vaccines. A few of the tests and vaccines use LMOs. The OIE has had a working group on biotechnology since 1996.

The Food and Agriculture Organization

2.3.25 The Food and Agriculture Organization (FAO) is a specialized agency of the United Nations that leads international efforts to defeat hunger. Its goal is to achieve food security for all and make sure that people have regular access to enough high-quality food to lead active, healthy lives. The FAO hosts an online platform for genetically modified foods. The FAO GM Foods Platform is a simple online platform to share information on safety assessment of foods derived from recombinant-DNA plants authorized in accordance with the Codex Guideline for the conduct of food safety assessment of foods derived from recombinant-DNA plants. This Platform also facilitates the effective utilization of food safety assessment in situations of Low Level Presence (LLP) of r-DNA plant materials in food. The Platform is freely accessible for those who want to browse the information. Registration is required for those who need to upload information (for example Focal Points).

2.4 Policy and Legislative Framework

Laws

2.4.1 The principal pieces of legislation which relate directly or indirectly to the regulation of LMOs in Jamaica are:

a) The Plants (Quarantine) Act, 1994
   - The Plants (Importation) Control Regulations, 1997 (amended in 2005);

b) The Animals (Diseases and Importation) Act, 1948 (amended in 1969)
c) The Bees Control Act, 1918 (amended in 1968)
d) The Natural Resources Conservation Authority Act, 1991
e) The Food and Drugs Act, 1975 (amended 1996)
f) The Standards Act, 1969 (amended 2002)
g) The Pesticides Act, 1987 (amended 1996)
h) The National Commission on Science and Technology Act, 2007

i) The Protection of Plant Genetic Resources for Food and Agriculture Act, 2013 (amended in 2019)
j) The Public Health Act, 1985
j) Customs Act, 1954 (amended in 2018)
k) Patent Act, 1857
l) Consumer Protection Act, 2005 (amended in 2013)
m) Dangerous Drugs Act, 1948 (amended in 2013)
n) Scientific Research Council Act, 1960 (amended in 2007), and
o) The Pharmacy Act, 1975

A list of the relevant policies and legislation is set out in **Appendix 1**.

2.4.2 The legislative review completed under the 2002 GEF/UNEP Biosafety Project that "the legislation was sectoral and in totality did not treat comprehensively with the issues. A decision to use the existing legislative framework would therefore require amendments to several pieces of legislation". It further noted that these amendments would need to address not only the substantive biosafety issues, but also issues of competence with respect to decision-making and the establishment of rules and regulations within each sector.

2.4.3 The Plants (Quarantine) Act, 1993 regulates the importation of plant species and establishes controls on plant pests. In addition to quarantine procedures, the Act empowers the Minister to prohibit the importation of any plant, article or thing from any country, where he is satisfied that plant pests may be introduced into the island. This would apply to any LMO that can be classified as a 'plant pest'.

2.4.4 The Plants (Importation) Control Regulations, 1997 under the Plants (Quarantine) Act, 1993 is the only legal instrument that directly addresses the issue of biosafety. The Regulations were enacted in 1997 and amended in 2005. Under these Regulations the National Biosafety Committee is legislated to monitor the importation of any plant, seed, cutting or slip, which has been genetically modified and imported into Jamaica for the purpose of experimentation. The NBC has monitored both the importation of transgenic material as well as experimental transgenic trials being conducted in Jamaica.

2.4.5 The Animals (Diseases and Importation) Act 1948 requires imported animals such as birds, reptiles and insects to be subject to a quarantine procedure.

2.4.6 The Bees Control Act, 1918 regulates the importation of bees and honey into the island. It also prescribes actions to be taken where diseases are found in apiaries.

2.4.7 The Natural Resources Conservation Authority (NRCA) Act, 1991 establishes the Authority, and has among its functions 'the capacity to take the necessary steps to manage the physical environment of Jamaica so as to ensure the conservation, protection and proper use of its natural resources'. The scope of its statutory mandate is sufficiently broad to address various biosafety issues and the possible impact of LMOs on human health and biodiversity. Under the Natural Resources Conservation (Permits and Licences) Regulations, the introduction of species of flora, fauna and genetic material and the introduction of living modified organisms require a permit from the NRCA.

2.4.8 The Ministry of Health (MOH) regulates the importation, sale, labelling, packaging and advertising of food and drug products under the Food and Drugs Act, 1975 as well as the Pharmacy Act, 1975.

2.4.9 The importation, manufacture, sale, labelling and use of pesticides are regulated by the Pesticide Control Authority by way of the Pesticides Act, 1975, and may thus affect LMOs being utilised for pest control purposes.

2.4.10 The National Commission on Science and Technology Act, 2007 includes a provision for the Commission to "develop, review and recommend to the Government, policies designed to facilitate the use of science and technology to enhance the efficiency, competitiveness and profitability of the productive sector and the sustainability of the environment and natural resources."

2.4.11 The Scientific Research Council Act, 1988 makes reference to the development and adaption of technologies which could include the development of LMOs.

2.4.12 The Protection of Plant Genetic Resources for Food and Agriculture Act, 2013 was approved by Parliament in January 2013. The objects of the Act are to facilitate Jamaica's compliance with its obligations under the International Treaty on Plant Genetic Resources for Food and Agriculture and otherwise to further the conservation and sustainable use of plant genetic resources and facilitate access to and use of plant genetic resources and to promote the equitable sharing of benefits arising from their use.

Policies

2.4.13 The principal policies which address issues related to biotechnology are the Biotechnology Policy for Economic and Social Development (draft) which includes a focus on research and development activities, and the Science and Technology for Socio-Economic Development: A Policy for Jamaica (draft). The latter is a revision

of the Science and Technology Policy of 1990, which recognizes biotechnology as a priority area, particularly in relation to agricultural, crop and animal production as well as research and development activities. It recognizes the need to manage the use of the island's biological resources and to build additional capacity in biotechnology. The revised draft policy reflects current issues in the field.

2.4.14 The Foreign Trade Policy, 2018 highlights the need to strengthen Jamaica's capacity to regulate the trade in LMOs to protect consumers from any potential harmful effects of LMO products.

2.4.15 A comprehensive policy for agriculture is being developed, but the current agricultural programme is guided by a Food Security Strategy and the Vision 2030 Agriculture Sector Plan which aim to improve productivity and production in the agricultural sector using new technologies, including biotechnology, in areas such as crop development and disease control and crop/land yield.

2.4.16 The more recent agricultural policies being developed make reference to the objectives of the biosafety policy. A list of other relevant policies is included in Appendix 1.

2.5 Existing Institutional Arrangements

2.5.1 The entities involved in addressing biosafety issues, at the national level are:

i. The National Biosafety Committee is the core national institution with direct oversight for biosafety issues. The Committee has been mandated to develop procedural guidelines for the importation of plant LMOs for experimentation. This Committee is also responsible for granting permission for the importation of plant[8], seed, cutting or slip under the Plants (Importation) Control Regulations.

ii. The institutions that are represented on the Committee include government ministries and agencies, as well as, academic and research institutions and a non-governmental organization.

iii. The National Commission on Science and Technology (NCST) is a statutory body under the Ministry with responsibility for science and technology[9] with

[8] "Plant" is defined to mean a plant that has been genetically modified and imported into Jamaica for the purpose of experimentation under controlled conditions

[9] Currently the Ministry of Science, Energy and Technology (MSET)

responsibility for advancing the national policy and strategy for science and technology and is the organization under whose auspices the NBC was established.

iv. The Ministry responsible for the environment (MRE) has the responsibility for the development of policies and legislation on environmental issues including the protection of biodiversity. The MRE is the Focal Point for the Cartagena Protocol on Biosafety as well as the Convention on Biological Diversity.

v. The Ministry with responsibility for agriculture (MRA), through its Plant Quarantine/Produce Inspection Branch and Veterinary Services Division (VSD), regulates the importation of plants and animal species respectively. Both divisions in collaboration with the Jamaica Customs Agency (JCA) are indirectly involved in regulating the transboundary movement of living modified organisms. Additionally, the Post Entry Quarantine Facility in the MRA, serves as a secure location for holding plants for further inspection or growth when imported into the island. The Post Entry Quarantine Facility also houses the germplasm for plants in Jamaica. The management of plant genetic resources is the responsibility of the Principal Director of Research and Development in the MRA. The Rural Agricultural Development Authority (RADA), an agency of the MRA, provides extension services to farmers.

vi. The Cannabis Licensing Authority (CLA), an agency of the Ministry of Industry, Commerce, Agriculture and Fisheries. It was established in 2015 under the Dangerous Drugs Amendment Act (2015), with the specific role to establish and regulate Jamaica's legal ganja and hemp industry. Its mandate is to:

    - To create regulations to guide the development of an orderly legal ganja and hemp industry in Jamaica for the use of the plant and its by-products for medical, therapeutic and scientific purposes.
    - To ensure that regulations created and activities within the industry are in keeping with Jamaica's international obligations
    - To issue licences, permits and authorisation for the handling of hemp and ganja.

vii. The Banana Board was established under the Banana Board Act of 1953 and its affairs are closely intertwined with those of the Banana Insurance Act of 1946. The Banana Board is a statutory body and is governed by a Board of Directors, which is comprised of five members, all of whom are appointed by the Minister with responsibility for Agriculture and Fisheries. The Banana

Board is the main institution through which the Government will make its interventions in the sector and be primarily responsible for performing *inter alia* the following functions:

- Establishing and monitoring standards for the industry
- Research and development of the banana industry
- Providing planting material/germplasm to banana farmers

viii. The Jamaica Agricultural Commodities Regulatory Authority (JACRA) is a statutory body which falls under the MRA. It is responsible for the regulation, promotion, standardization and development of the agricultural commodities industry – which includes cocoa, coffee, coconut and the spices (nutmeg, pimento, ginger and turmeric). This includes definition of quality standards, growing areas, recommending plant varieties and certifying quality of the commodities, sample testing, handling of export documentation and preparation. In addition, the JACRA is responsible for the provision of information and capacity building resources to farmers and other relevant stakeholders as well as research and development activities pertaining to quality standards and international best practices.

ix. The National Environment and Planning Agency (NEPA) implements, *inter alia*, the regulatory framework for environmental protection on behalf of the Natural Resources Conservation Authority.

x. Various tertiary and research bodies, including departments within the University of the West Indies (UWI), the Scientific Research Council (SRC), Bodles Research Station, Sugar Industry Research Institute, College of Agriculture, Science and Education, Northern Caribbean University, University of Technology and the Coconut Industry Board are engaged in or connected with the development or application of biotechnology research. Transgenic research is currently being done at the UWI's Biotechnology Centre/Department of Life Sciences.

xi. The Bureau of Standards Jamaica (BSJ) is the government entity with responsibility for setting national standards as it relates to trade and commerce.

xii. The National Compliance Regulatory Authority (NCRA) regulates and monitors the application of standards to different aspects of trade and commerce including labelling standards. The NRCA monitors all food manufacturing facilities.

xiii. The Consumer Affairs Commission Jamaica (CAC) is dedicated to protecting the interests of consumers through educational programmes, among other things.

xiv. The Institute of Jamaica (IOJ) is the national focal point for the Biosafety Clearing House established under the Cartagena Protocol to facilitate the exchange of biosafety information among countries. The Natural History Museum of Jamaica of the IOJ currently hosts the National Biosafety Clearing-House.

xv. The Ministry of Foreign Affairs and Foreign Trade is responsible for, *inter alia*, the negotiation of international and regional trade agreements and the formulation of country's trade policy.

xvi. The Ministry of Health plays an important part in the establishment, enforcement and monitoring of standards. It is also responsible for the implementation of the provisions of the Public Health Act.

3. THE POLICY

3.1 Vision and Values

3.1.1 Vision Statement

Jamaica has an enabling environment for the safe development and utilization of modern biotechnology, resulting in minimal risks to human health and biodiversity while providing benefits to economic sectors, including health, agriculture and industry.

3.1.2 Principles and Values

This Policy is a key tool to support Jamaica in meeting its obligations in ensuring the safe handling, transport and use of living modified organisms (LMOs) resulting from modern biotechnology that may have adverse effects on biological diversity, taking also into account risks to human health. The Policy is based on an approach to biotechnological development that balances possible risks against potential benefits. The principles and values that underlie the interpretation and implementation of this Policy are:

3.1.2.1 The Precautionary Approach: Where there are threats of serious or irreversible damage to human health or the environment, lack of scientific certainty shall not be used as a reason for postponing cost-effective measures to prevent environmental degradation or harm to human health.

3.1.2.2 Primacy of Public Health and Environment: The economic benefits that could potentially result from the development or importation of LMOs and derived products will be weighed against their impact on public health and the environment in keeping with Section 13(3)(l) of the Charter of Fundamental Rights and Freedoms of Jamaica. The primacy of public health and environmental considerations should take precedence when decisions are to be made with respect to the refusal of entry, or imposition of conditions and restrictions where necessary and their strict enforcement as they relate to biosafety issues.

3.1.2.3 Enabling Environment for Resource Development: The local development and promotion of modern biotechnology are critical to Jamaica's advancement and its future positioning in an evolving global marketplace. The implementation and monitoring of biosafety standards will assist in creating an enabling environment for biotechnology.

3.1.2.4 Shared and Accessible Benefits: Measures will be established to ensure the equitable sharing of benefits arising from the use of modern biotechnology across various sectors and industries. These measures will be based on ensuring the principle of inter-

generational and intra-generational equity applies to the access, use and benefits of biotechnology in Jamaica.

3.1.2.5 Public Awareness and Participation: The right of the public to be made aware of and as such, be able to make informed choices on their level of exposure to or consumption of LMOs and derived products will be fulfilled and protected. Public participation in policy development and transparency in decision-making are key elements.

3.1.2.6 Effective access to judicial and administrative proceedings, including redress and remedy: The right of the public to have access to effective judicial and administrative proceedings including mechanisms for redress and remedies will be included in the legislative framework.

3.2 Policy Goal and Objectives

Goals

The goals of the Biosafety Policy for Jamaica are:

1. To manage the risks to human health, agriculture and biodiversity from the development, transboundary movement, handling and use of living modified organisms; and
2. To facilitate the development of a national modern biotechnology sector in a safe and regulated environment.

Objectives

The main objectives of the National Biosafety Policy are to:

1. ensure the effective regulation of the transboundary movement (import and export) of LMOs is in keeping with the relevant international rules and standards as well as the tenets of the Cartagena Protocol on Biosafety;

2. ensure that the possible adverse effects of LMOs on human health and biodiversity are effectively mitigated and managed;

3. promote the development and utilization of modern biotechnology at the national level that may provide financial benefits to the relevant sectors taking into account issues of biosafety;

4. establish national standards, in keeping with international standards, for the safe handling, storage, transport, detection, identification and use of LMOs, including packaging, labelling, documentation, disposal and contingency procedures;

5. increase public education and awareness and information sharing on biosafety to facilitate effective implementation of the national biosafety regime; and

6. increase the capacity of the relevant national institutions to implement and monitor a national framework for biosafety.

LMOs which are pharmaceuticals for humans are not addressed in this Policy. It should be noted however, that this category of LMOs is covered under the legislation and policies related to drugs under the mandate of the Ministry of Health.

3.2.1 OBJECTIVES

Objective 1: Ensure the effective regulation of the transboundary movement (import and export, of LMOs is in keeping with international rules and standards as well as the tenets of the Cartagena Protocol on Biosafety

The Cartagena Protocol provides global standards for regulating the transboundary movement of LMOs. The implementation of its provisions facilitates harmonization of the local regulatory environment and that which exists in other markets/jurisdictions, as well as, the management of any potential adverse effects of LMOs. In the identification of strategies to fulfill this objective, the provisions of the Cartagena Protocol related to the following areas will be applied:

- transboundary movement of LMOs:
    - notification procedures;
    - identification, handling, packaging and transport;
    - decision-making procedures and review of decisions (including reference to national and regional nodes of the Biosafety Clearing-House);
    - unintentional and illegal transboundary movements; and
    - emergency measures;
- LMOs in transit.

In keeping with the tenets of the Cartagena Protocol, this section does not apply to LMOs being imported for direct use as food, or feed or for processing (FFP). This category of LMOs shall instead be addressed within the scope of the regulation of LMOs for domestic use, as further defined under Objective 2 below.

Objective 2: Ensure that the possible adverse effects of LMOs on human health and biodiversity are effectively mitigated and managed

The potential adverse effects that LMOs may have on human health, biodiversity and natural ecosystems must be identified, evaluated and risks mitigated. LMOs imported or developed locally for direct use as FFP must also be safely managed. LMOs imported for direct use as FFP will be subject to the risk assessment procedures outlined in **Appendix III** and the information required in **Appendix II** must be provided. The management of risks is related not only to the external trade and transboundary movement of LMOs, but to activities within the local biotechnology industry.

This policy objective will be implemented under five main areas:

- Risk Assessment and Management;
- Assessment of Socio-Economic Impact;
- Regulation of LMOs in Domestic Use;
- Promotion of Safe Practices; and
- Standards for contained use, field trials and intentional release.

Objective 3: Promote the development and utilization of modern biotechnology at the national level that may provide financial benefits to the relevant sectors taking into account issues of biosafety

Living modified organisms can provide benefits in areas such as agriculture that are not available using traditional breeding methods. The application of genetically modified techniques to crops has the potential to:

- increase agricultural productivity through the development of disease and pest resistant crops and drought tolerant crops;
- increase shelf life;
- increase nutritional value;
- reduce use of pesticides providing environmental and economic benefits; and
- minimize human exposure to pesticides.

Objective 4: Establish national standards, in keeping with international standards, for the safe handling, storage, transport, detection, identification and use of LMOs, including packaging, labelling, documentation, disposal and contingency procedures

In keeping with the requirement for the safe use and handling of LMOs, as well as the requirement for keeping the public informed of the nature and characteristics of LMOs to which it is exposed, local standards for the labelling of LMOs:

(a) intended for direct use as FFP;
(b) destined for contained use; or
(c) intended for intentional introduction into the environment

must be developed in keeping with the relevant international rules and standards. These standards should be applied to LMOs being introduced into the domestic market, LMOs being stored, transported or used for research or field production purposes, as well as LMOs being brought into the island for aid relief.

Protocols for the safe handling, transport, packaging, storage, identification and use of LMOs will also be developed.

Objective 5: Increase public education and awareness and information sharing on to facilitate effective implementation of the national biosafety regime

Public awareness and participation in policy implementation and decision-making is one of the principles on which any national biosafety regime is based. The responsibility for informing the public on biosafety and modern biotechnology must be executed through ongoing and multi-sectoral initiatives. In keeping with the policy of the Government of Jamaica on public consultations on policy decisions, the participation of the public in the implementation and subsequent reviews of the biosafety policy will also be promoted. The relevant laws related to biosafety issues will be reviewed and amended as appropriate to include provisions to facilitate public participation in the decision-making processes regarding LMOs and the mechanisms by which such decisions will be made available to the public respecting confidential information.

The BCH will promote the sharing of scientific, technical and legal information concerning the development, transboundary movement, handling and use of LMOs, and the management of any possible adverse effects arising from LMOs.

While public awareness material and the flow of public information will be proactively facilitated through the BCH, the public can also access specific information by making a request under the Access to Information Act[10]. Additionally, relevant public sector agencies will have responsibility for disseminating information to the public based on their respective mandates, for example the Ministry of Health and the CAC.

Special public education and awareness programmes will be developed and implemented taking into account the specific needs of vulnerable groups including low-income households, persons with low literacy levels and the farming community. The dissemination of information will be done not only by traditional means, but all available methods, sources and modern technologies, including webinars and social media, and a combination thereof, as appropriate, will be utilized.

Objective 6: Increase the capacity of national institutions to implement and monitor a national framework for biosafety

The effective implementation of this Policy will require the upgrading of technologies and human resource capacities within the relevant public sector regulatory agencies. This will require Government's commitment to continuously increase the capacity of these ministries, departments and agencies (MDAs). Where resources exist in the private sector, public-private partnerships will be pursued to increase the country's capacity to effectively manage biosafety issues.

Effective implementation of the Policy will require the development of new operational procedures, the training of staff as well as investment in equipment and technology to improve capacity to facilitate the detection and identification, transboundary movement, safe handling, transport, packaging, identification and use of LMOs. Existing facilities, such as the UWI Biotechnology Centre and the SRC will be critical in providing the necessary training and research. The IOJ, in its capacity as the Biosafety Clearing-House (BCH) National Focal Point, will publish information to the online BCH Portal in consultation with designated Competent National Authorities. This information will include decisions to import or develop LMOs, and information for facilitating "the exchange of scientific, technical, environmental and legal information on, and experience with, living modified organisms"[11].

[10] http://moj.gov.jm/sites/default/files/laws/The%20Access%20%20to%20Information%20Act.pdf
[11] cbd.int

4. FRAMEWORK FOR IMPLEMENTATION AND MONITORING

The effective implementation of this Policy requires the clear delineation of responsibilities and coordination among a number of public sector agencies and the private sector. The objectives of setting up administrative systems for biosafety are three-fold:

- Establishing and developing competent national authorities;
- Establishing the procedures for processing applications, risk assessment, risk management, decision-making, monitoring, inspection and enforcement;, as well as
- Public awareness, education and participation.

A sound national institutional framework is therefore necessary to coordinate, regulate and enforce biosafety matters in the country.

4.1 *Implementation Framework*

4.1.1 At the national level, the approach to implementation will be multi-sectoral, involving the collaboration and input of various MDAs. The Ministries with responsibility for the environment and agriculture will be responsible for policy development and monitoring of implementation, review and modifications of the policy based on prevailing best practises and global standards.

4.1.2 Central to the implementation of the Policy is the establishment and effective operation of a National Biosafety Committee.

The National Biosafety Committee (NBC)

4.1.3 The Ministry with responsibility for the Environment (MRE) will establish a National Biosafety Committee (NBC) which will be responsible for the reviewing of applications for the importation of LMOs, safe handling, containment and disposal of LMOs, reviewing field research reports involving LMOs, assisting with developing and reviewing guidelines and standards and material for public and sector-specific education and awareness raising. Activities related to education and awareness will assist in raising awareness and strengthening cooperation and coordination between competent authorities and other stakeholders, including the private sector, civil society and development partners. The members of the NBC shall include senior officers of:

- Ministry with responsibility for agriculture and fisheries:
    - Research & Development Division;
    - Plant Quarantine/Produce Inspection Branch;
    - Veterinary Services Division;

- Ministry with responsibility for health;
- Ministry of Foreign Affairs and Foreign Trade;
- Ministry with responsibility for the environment (Environment and Risk Management Branch)
- Natural Resources Conservation Authority/National Environment and Planning Agency
- Scientific Authority (appointed under the Endangered Species (Protection, Conservation and Regulation of Trade) Act)
- Ministry with responsibility for science and technology;
    - Scientific Research Council
    - National Council on Science and Technology
- Ministry with responsibility for Industry and Commerce
    - Bureau of Standards Jamaica
    - National Compliance Regulatory Authority
    - Consumer Affairs Commission
- Ministry with responsibility for finance
    - Jamaica Customs Agency
- Ministry with responsibility for culture and gender
    - Institute of Jamaica
- Tourism Product Development Company
- At least one representative from the private sector (health, agriculture, tourism)
- At least one representative from academia, and
- At least one representative from civil society.

4.1.4 Other persons/agencies with identified expertise areas related to biosafety, as well as NGO representation, may be co-opted to the Committee, as necessary. NEPA will serve as the secretariat for the NBC.

4.1.5 The appointment of the members, as well as the constitution and procedures of the NBC will be enshrined in law.

Competent National Authorities

4.1.6 In keeping with Article 19(1) of the Cartagena Protocol which states 'Each Party shall ….designate one or more competent national authorities, which shall be responsible for performing the administrative functions required by this Protocol and which shall be authorized to act on its behalf with respect to those functions. A Party may designate a single entity to fulfil the functions of both focal point and competent national authority….'. In this regard, the Policy prescribes that these administrative

functions be assigned to various designated competent authorities as per their existing legal or administrative mandate, as follows.

4.1.7 Competent authorities will be established designated to treat with for different types categories of LMOs. The competent authorities that will be designated are: (i) the Natural Resources Conservation Authority (NRCA)/NEPA, (ii) the Ministry with responsibility for Health (MRH) and (iii) the Ministry with responsibility for Agriculture and Fisheries. These competent authorities will be responsible for carrying out the administrative functions required by the Cartagena Protocol.

4.1.8 Regarding the role of the NRCA as a competent national authority, the National Environment and Planning Agency (NEPA) will be responsible for receiving applications under the NRCA Permit and Licences Regulations and responding to and making decisions on notifications and applications in consultation with the NBC. The NRCA in consultation with the NBC will be responsible for making determinations for any proposed releases to the environment. The information relating to decision-making will be posted on the Jamaica Biosafety Clearing-House at the IOJ.

4.1.9 The Ministry of Health will be the competent authority responsible for the regulation of LMOs used in the health sector where these fall under the ambit of the Cartagena Protocol. Applications will be made to the Ministry of Health and in consultation with the NBC, a determination on the application will be made. The decision will be posted on the Jamaica BCH at the IOJ.

4.1.10 The Ministry with responsibility for Agriculture and Fisheries will be the competent authority responsible for the regulation of all LMOs used in agriculture and aquaculture.

<u>Decision-making process</u>

4.1.11 Parties of export will notify the relevant CNA of intended transboundary movements of LMOs. The CNA will refer these applications to the NBC for a recommendation. Based on the recommendation of the NBC, the CNA will communicate its decision to the Party of export and issue the relevant licence/permit as required.

<u>Role of the Ministry with responsibility for the environment</u>

4.1.12 The MRE in its capacity as the National Focal Point for the Cartagena Protocol, will be responsible for liaising with the secretariat of the Cartagena Protocol regarding Jamaica's implementation of the provisions of the agreement, including the

transmission of national reports on biosafety, at such intervals as determined by the Conference of the Parties serving as the Meeting of the Parties to the Protocol.

Transboundary movements of LMOs

4.1.13 The NBC will develop recommendations for the regulation of the transboundary movement (importation and exportation) of LMOs between Jamaica and Parties and non – Parties as per the standards prescribed in international rules and standards, including the Cartagena Protocol on Biosafety. The National Biosafety Clearing – House, hosted by the IOJ, will serve as a means through which information on transboundary movements is made available to other international biosafety information exchange mechanisms.

Bilateral, Regional, Multilateral Agreements and Arrangements

4.1.14 The MFAFT, in consultation with the relevant stakeholders, will be responsible for entering into bilateral, regional, multilateral agreements or arrangements regarding international transboundary movement of LMOs in keeping with the provisions of the Cartagena Protocol.

4.1.15 Final agreements/arrangements will be communicated by MFAFT to the IOJ in its capacity at the host for the National BCH.

Information Sharing

4.1.16 The IOJ as the designated national BCH, will receive information from all relevant agencies, and share this information with local and international stakeholders. The BCH will house a catalogue of all the entities involved in biosafety research to facilitate the timely dissemination of data and information that can impact public health and food security. The Competent Authorities, namely NRCA/NEPA, the Ministry with responsibility for Agriculture and Fisheries and MOH, will be primarily responsible for preparing material for public education. The CAC will assist in the preparation and dissemination of information on biosafety to the general public as well as the development of the modalities for public participation in LMO decisions.

Monitoring and Enforcement

4.1.17 The National Environment and Planning Agency will have a critical role in monitoring and enforcement especially as it relates to the potential impact of LMOs on the country's biodiversity.

4.1.18 It is not envisaged that new institutions will be created in the short-term to address the processing of applications. However, specific implementation functions will be integrated into the related mandates of a range of government entities: the roles of agencies may be enhanced and coordinated for efficient response to notifications, risk management, monitoring and enforcement and sharing of information. Departments and agencies such as NEPA and the Plant Quarantine/Produce Inspection Branch and Veterinary Services Division will continue to carry out their specific roles regarding the issuing of permits in relation to requests for importation of LMOs.

Registration of Biosafety Entities and Practitioners

4.1.19 A process of mandatory registration, monitoring and evaluation of all entities and practitioners involved in or associated with Biosafety research will be instituted. Registration will be carried out by the appropriate government body (SRC).

Role of other Ministries, Departments and Agencies

4.1.20 Among other key roles are those of:

- the **Ministry with responsibility for Agriculture and Fisheries** Plant Quarantine/Produce Inspection Branch and Veterinary Services Division which are involved in the processing of applications for food, or feed, or for processing and monitoring in the field and RADA, which relates directly with farmers and may provide information and advice;
- the **Bureau of Standards Jamaica** which will develop standards, inter alia, for labelling and packaging;
- the **Jamaica Customs Agency,** the **Bureau of Standards Jamaica**, and the **National Compliance Regulatory Authority** will be responsible for the regulation of the import/export of LMOs at the ports; and
- **Organizations that benefit from government funding and/or regulation**, in particular universities and research entities will also be involved in implementing the relevant biosafety strategies.

Figure 1 illustrates the institutional roles and responsibilities of the various entities/agencies through which this policy will be implemented.

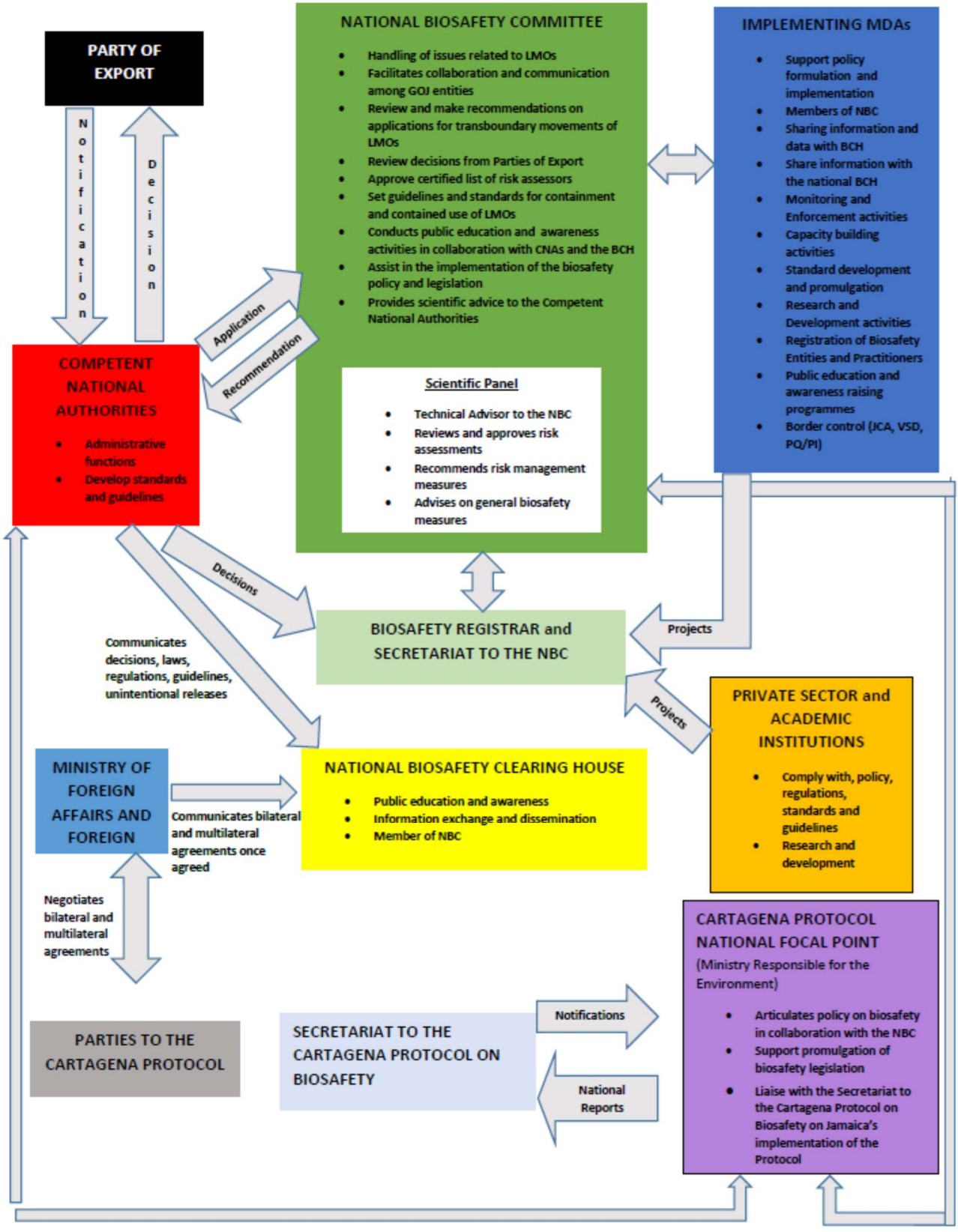

Figure 1: National Biosafety Framework

4.2 *Implementation Strategies*

Objective 1: Ensure the effective regulation of the transboundary movement (import and export) of LMOs is in keeping with the relevant international rules and standards as well as the tenets of the Cartagena Protocol on Biosafety

4.2.1 Movement of LMOs

Biosafety legislation will be developed as a priority to encompass all aspects related to, *inter alia*, transboundary movement of LMOs, LMOs in-transit, in country movement of LMOs and information sharing with other countries Party to the Convention on Biological Diversity in keeping with international standards. The National Biosafety Committee (NBC) will ensure the effective implementation of this regulatory mechanism. The NBC will also monitor the requisite sharing of decisions and notifications by all relevant entities with the BCH.

The Ministry of Foreign Affairs and Foreign Trade will also enter into bilateral, regional and multilateral agreements and arrangements regarding intentional transboundary movements of living modified organisms on the advice of the NBC.

Objective 2: Ensure that the possible adverse effects of LMOs on human health and biodiversity are effectively mitigated and managed

4.2.2 Risk Assessment and Management

4.2.2.1 Risk Assessment

i. The competent authority(ies) in consultation with the NBC, as appropriate, will make informed decisions regarding LMOs based on a review of the risk assessments conducted or reviewed by the Scientific Panel. The NBC will also provide general scientific advice, including in the area of risk management, to the competent authority(ies).

ii. The NBC will develop, and continually update, risk assessment procedures applicable to the import/export, use, handling, research and development of LMOs. Risk assessment procedures will be developed and implemented in a scientifically sound manner and will reflect international standards, particularly those set out in the Cartagena Protocol.

iii. A risk assessment can be undertaken by any entity or person (including the importer) but must meet the approval of the Scientific Panel prior to consideration of any application related to the use, handling or transboundary movement of an LMO. The assessment shall include approvals regarding the importation of LMOs.

iv. Risk assessments may also be undertaken on the use of modern biotechnology research being conducted by locally-based tertiary or scientific institutions, whenever a *prima facie* case arises that suggests that such an assessment is necessary for the prevention of possible harm to human health and biodiversity. Notwithstanding the existence or outcomes of previous assessments, a risk assessment should always be conducted for first time release of an LMO into the environment to determine the possible adverse effects on the conservation and sustainable use of biological diversity and the risks to human health.

v. The NBC in reviewing applications related to the use, handling or transboundary movement of an LMO will take into account all risk assessment(s) in relation to:

    a. the relative impact of, or risks associated with similar, non-modified organisms; and
    b. the social, economic or environmental impact that is likely to result from the introduction of the LMO into the environment

    prior to making its recommendations to the CNA

vi. The cost of conducting a risk assessment shall be borne by the applicant (party) whose products, research or systems are being assessed.

vii. The risk assessment may, at the request of and/or on the approval of the NBC, be conducted by any competent public or private entity.

viii. Where there is insufficient data to carry out a thorough assessment of risks, the 'precautionary approach' should be applied in decision-making.

ix. Risk assessment procedures and summary reports on assessments undertaken (excluding any confidential or protected information) shall be forwarded by the respective CNAs to the BCH**.**

4.2.2.2 Risk Management

The Scientific Panel will develop or identify risk management mechanisms, measures and strategies to regulate, manage or control the risks associated with the development, use,

release and transboundary movement of LMOs resulting from biotechnology which are likely to have adverse environmental impacts and risks to human health.

The implementing agencies as identified in Figure 1 will be required to implement any risk management mechanisms, measures and strategies developed or identified by the Scientific Panel of the NBC.

The NBC will periodically evaluate the effectiveness and feasibility of such measures and strategies.

The relevant agencies (including Plant Quarantine/Produce Inspection Branch, Veterinary Services Division and NEPA) will monitor the implementation of the risk mitigation/management measures and enforce such measures in accordance with Article 16 of the Cartagena Protocol. NEPA, the Ministry with responsibility for Agriculture and Fisheries and the Ministry of Health will identify LMOs or specific traits of LMOs that may have adverse effects on conservation and sustainable use of biological diversity, taking into account the risks to human health.

4.2.3 Assessment of Socio-Economic Impact

i. The NBC may recommend that the appropriate agency may restrict, prohibit or attach conditions to the use or introduction of an LMO into the environment and/or market where it appears that such use or introduction is likely to result in significant, adverse socio-economic impact.

ii. The NBC will set parameters for the socio-economic impact assessment of an LMO. In so doing the NBC will be guided by, among other factors, the extent to which the use (including illicit or off-label uses) or introduction of the LMO poses a threat to:
    a. the livelihood of a local community;
    b. a practice that is considered part of the national culture or heritage; and/or
    c. human health.

iii. Any organization, community, group of persons or an individual claiming the adverse potential or actual effects of the use or introduction of an LMO shall make a submission to the competent authority for consideration by the NBC that clearly sets out:
    a. the nature of the adverse effects of the use or introduction of the LMO;
    b. evidence of the causal links between the LMO and such effects, where possible; and
    c. recommended restrictions on the use or introduction of the LMO.

4.2.4 Regulation of LMOs for Domestic Use

i. The competent authority in consultation with the NBC will put in place a regulatory system for the safe management of LMOs for domestic use. This will cover LMOs imported or developed locally for use as FFP, as well as, LMOs in contained use. Within this regulatory framework, the decision-making procedures will be consistent with the requirements and objectives of the Cartagena Protocol, and includes the following:
    a. all final decisions affecting an LMO for domestic use that may be subject to transboundary movement for use as FFP will within 15 days be sent to and communicated through **the BCH** to international stakeholders, in the format required and according to the guidelines set by the Cartagena Protocol;
    b. guidelines and approval processes for the importation of LMOs intended for use as FFP should be consistent with the vision and principles of this policy and should not pose any undue risk to human health and biodiversity. Copies of such guidelines will be forwarded to **the BCH in advance of approval for the importation of LMOs**; and
    c. decisions will be made on the basis of:
        - available scientific information and/or the findings of a risk assessment; and
        - the application of the precautionary approach.

ii. The competent authority will, in collaboration with the NBC, develop guidelines regarding the handling, storage, transportation and disposal of LMOs in domestic and commercial use and for research purposes.

iii. Copies of all guidelines and other regulatory instruments developed for LMOs in domestic use will be forwarded to **the BCH**.

4.2.5 Promotion of Safe Practices (Handling, Transport, Packing and Identification)

i. The NBC will develop guidelines for the development and implementation of internal safety procedures for public or private organizations engaged in modern biotechnology research or the use, transportation, storage or handling of LMOs;

ii. Every publicly funded programme engaged in modern biotechnology research or whose personnel are engaged in the use, transportation, storage or handling of LMOs shall develop and implement internal safety procedures. Programmes shall include, but not be limited to, the following:
    a. tertiary institutions receiving government grants or subventions;

b. departments and agencies under the MRE, Ministry with responsibility for Industry and Commerce, Ministry with responsibility for Agriculture and Fisheries, MOH, Ministry with responsibility for Science and Technology or any other line ministry, in which personnel are directly exposed to LMOs; and
c. the Jamaica Customs Agency and ports of entry.

iii. As a pre-condition to the approval of grants, incentives or other forms of State support to private organizations or the entry into public-private partnership with any tertiary or scientific research institution, such organizations or institutions shall be required to develop internal safety procedures reflecting the guidelines developed by the NBC.

iv. Safety procedures should, among other things, provide for the accurate labelling and identification of LMOs (detailed below) and should endeavour to limit the possibility of accidental introduction of the LMO into the environment.

v. Safety procedures must also include guidelines for their monitoring, enforcement and compliance management. These should include:
a. provisions for the wide dissemination of the procedures among personnel;
b. orientation protocols for new personnel;
c. intermittent process audits; and
d. penalties for procedural breaches.

vi. Copies of all safety guidelines developed by the NBC shall be forwarded to the BCH.

4.2.6 Standards for contained use, field trials and deliberate release

i. The competent authority will, in consultation with the NBC, develop standards for the handling of LMOs that are:
a. destined/being imported for contained use; and
b. being developed within Jamaica.

ii. The competent authority will, in consultation with the NBC, develop protocols for the establishment and monitoring of field trials and the deliberate release of LMOs into the environment.

iii. The competent authorities will develop certification standards for organizations developing and/or handling LMOs; and

iv Legislation will be enacted to address standards for contained use including field trials and deliberate release of LMOs.

Objective 3:
Promote the development and utilization of the modern biotechnology at the national level that may provide financial benefits to the relevant sectors taking into account issues of biosafety

4.2.7 Institutions to Promote Development and Utilization

i. Government agencies and institutions, including the Ministry with responsibility for Agriculture and Fisheries and the SRC will provide opportunities for staff training.

ii. The relevant government ministries will promulgate the Science, Technology and Innovation; and the Biotechnology policies.

iii. Institutions, such as the UWI, through the Biotechnology Centre, will be involved in the training of personnel in the technology.

iv. UWI, SRC and the Ministry with responsibility for Agriculture and Fisheries will conduct research in GM crops directed particularly to the needs of small farmers.

v. The BCH at the IOJ will be responsible for facilitating "the exchange of scientific, technical, environmental and legal information on, and experience with, living modified organisms"[12].

Objective 4: Establish standards for the safe handling, storage, transport and use of LMOs including packaging, labelling, documentation, disposal and contingency procedures, in keeping with international labelling standards

4.2.8 Labelling Standards and Institutions Responsible

i. The BSJ in collaboration with the NBC will develop standards, which will be reviewed on a periodic basis, for the labelling and identification of LMOs. In developing these standards, which will be enshrined in law, the NBC will take into account the labelling and packaging requirements under the Cartagena Protocol, as well as those recommended by other international bodies.

[12] cbd.int

ii. All relevant monitoring bodies, including the BSJ, the CAC, the NEPA, the Jamaica Customs Agency and the relevant departments under the Ministry with responsibility for Agriculture and Fisheries will be required to incorporate such labelling and identification standards in their ongoing monitoring regimes.

iii. At a minimum, the standards for labelling LMOs will include the following requirements:

a. all LMOs, whether in storage, in contained use, being transported, on the market, on display or which may otherwise be exposed to the public, should be clearly marked with language to the effect that it:
    - contains or may contain LMOs; and
    - is not intended for release into the environment (unless such release has been approved by the relevant authorities).

This information should be included on labels, packaging and signage, as well as in documentation accompanying the LMO.

b. labels, packaging and signage for LMOs being stored, transported, displayed or distributed should also include the following information:
    - the identity and relevant traits or characteristics of the LMO;
    - instructions for safe use, storage, transportation or handling;
    - instructions for preventing the unintentional release of the LMO into the environment; and
    - the name and contact information of the owner, distributor, importer, exporter, any party having custody of or responsibility for the LMO or any party authorized to give further information on the LMO;

c. LMOs that are being imported or exported should also be labelled with a declaration that the transboundary movement of the LMOs is in compliance with the standards of the Cartagena Protocol;

d. all labels, packaging and signage for LMOs are to be:
    - in English;
    - written or typed in a clear, legible font; and
    - conspicuously placed

iv. Copies of all such standards developed and any subsequent amendments must be submitted to the BCH.

Objective 5: Increase public education and awareness and information sharing on biosafety to facilitate effective implementation of the national biosafety regime

4.2.9 Public awareness and participation in biosafety policy implementation

i. The competent authorities in collaboration with the **NBC** will develop and implement an ongoing Public Education Programme on Biosafety, which shall include but not be limited to:
    a. FAQs, brochures and other easily distributed materials explaining the characteristics and principles of biosafety and the biosafety policy in simplified language, including means of access to the Biosafety Clearing-House;
    b. publication of this Biosafety Policy and related information in booklet format, will be widely distributed to all stakeholders, including the general public,, via the websites of the competent authorities as well as related information on social media;
    c. documentation of all forms, standards, guidelines and protocols related to biosafety and modern biotechnology, for print and electronic access by the public;
    d. stakeholder awareness-building fora, to be conducted island wide;
    e. special public education and awareness programmes taking into account the specific needs of vulnerable groups including, low income households, persons with low literacy levels and the farming community. The dissemination of information will be done not only by traditional means, but all available methods, sources and modern technologies, including webinars and social media, and a combination thereof, as appropriate, will be utilized; and
    f. personnel training sessions to be conducted within all public and private entities that will have direct input in the implementation of this Biosafety Policy.

ii. The **Ministry with responsibility for Agriculture and Fisheries,** the **MRE, the Ministry with responsibility for Industry and Commerce,** the **BSJ,** the **CAC, NEPA, NCST, SRC** and the **Jamaica Customs Agency** will, as appropriate, develop and disseminate public education and awareness raising materials and implement awareness activities and programmes on biosafety.

iii. The **MRE, NEPA** and the **NBC** will collaborate in promoting the inclusion of information on modern biotechnology and the tenets of the Biosafety Policy in:

a. the public education campaigns of public and private entities involved in public awareness building on issues related to science, the environment, agriculture and consumer protection; and
b. the curricula of vocational or tertiary institutions conducting training in the science, environmental or agricultural fields.

4.2.10 Transparency in Decision-making

Decision making will be in keeping with Articles 10 and 12 of the Cartagena Protocol on Biosafety. In keeping with the principles of good governance and transparency, the NBC and NEPA will endeavour to make available the reasons behind any decision in keeping with this Policy.

i. The competent authority and the NBC, at the request of an interested Party[13] (including interest groups) or on its own initiative, review previous decisions on any of the following grounds:
    a. a Party brings to the attention of the MRE/NBC new scientific data on the potential adverse effects of that LMO on human health or biodiversity;
    b. risks to human health and biodiversity have been increased or reduced in light of new or additional scientific or technical information; and
    c. a change in circumstances has occurred that may influence the outcome of a risk assessment on the basis of which the decision was made.

ii. Where a decision has been reviewed as provided above, **NEPA** shall send notices of its new decision, together with reasons to:
    a. the **Party** requesting the review;
    b. any **Party** affected by the decision(s) under review; and
    c. the **BCH,** for further notification to local and international stakeholders.

iii. Except as provided herein, all requests for information regarding decisions, procedures or practices falling within the scope of this policy shall be made in writing and conform to the requirements of the Access to Information Act.

[13] Any Party to the Cartagena Protocol on Biosafety

Objective 6: Increase the capacity of national institutions to implement and monitor a national framework for biosafety

4.2.11 Roles of Agencies for Capacity Building

i. **All competent authorities** will be required to include in their respective annual plans and programmes, strategies to implement this Biosafety Policy, including strengthening their capacities.

   The respective Ministries with responsibility for the competent authorities, as well as, the PIOJ will seek to identify and maximize opportunities for the strengthening of the capacities of the NBC and the competent authorities to effectively execute their mandates.

ii. The implementation of this Policy requires the capacity to test plants, animals and their products which are being imported or are the subject of research, in order to detect and identify the presence of LMOs. The competent authority in conjunction with the **Ministry with responsibility for agriculture and fisheries** and the **Jamaica Customs Agency** will build their respective capacities to facilitate testing, through the acquisition of equipment and the training of staff.

iii. **The Biosafety Registrar (NEPA)** will maintain a database of all projects and initiatives involving modern biotechnology research or the use of LMOs.

4.3 *Implementation Plan*

Policy Objective	Strategy	Key Activities	Indicators	Timelines	Responsible Agencies	Costs ($J)
Ensure the effective regulation of the transboundary movement (import and export) of LMOs is in keeping with the relevant international rules and standards as well as the tenets of the Cartagena Protocol on Biosafety	Implementation of an effective regulatory mechanism for the transboundary movement of LMOs, LMOs in-transit, in country movement of LMOs and information sharing with other countries Party to the Convention on Biological Diversity in keeping with international standards.	Establishment of National Biosafety Committee	National Biosafety Committee (NBC) established	Yr 1	MRE	Staff time
		Enshrining the NBC in law	Appropriate legislation amended or enacted regarding the appointment, constitution and procedures of the NBC	Yrs 1 -2	MRE	Staff time
		Draft legislation for the transboundary movement of LMOs, LMOs in transit, and in country movement of LMOs	Drafting instructions completed	Yr 1	MRE, NEPA, Ministry with responsibility for Agriculture and Fisheries,	Staff time

Policy Objective	Strategy	Key Activities	Indicators	Timelines	Responsible Agencies	Costs ($J)
		Implementation of effective regulatory mechanism for the transboundary movement of LMOs, LMOs in transit, and in country movement of LMOs	Regulatory mechanism implemented	Yr 3	NBC	Staff time
		Monitoring the requisite sharing of decisions and notifications by all relevant entities with the BCH	Requisite decisions and notifications shared by entities with the BCH	Yrs 1-5	NBC, National BCH	Staff time
		Development and updating of risk assessment procedures applicable to the import/export, use, handling, research and development of LMOs	Risk assessment procedures developed and implemented in a scientifically sound manner which reflects international standards particularly those set out in the Cartagena Protocol	Yrs 1-5	NBC	Staff time
		Take steps to ratify the Nagoya – Kuala Lumpur Supplementary Protocol on Liability and Redress to the Cartagena Protocol on Biosafety	Legal opinion regarding ratification obtained	Yrs 1-2	MRE, AGC	Staff time
Ensure that the possible adverse effects of LMOs on human health and biodiversity are	Risk assessment and management	Make determinations regarding LMOs based on review of the risk assessments conducted or reviewed by the Scientific Panel	Risk assessments reviewed in all deliberations by the Competent Authorities	Yrs 1-5	Lead: Competent Authorities Support: NBC,	Staff time

Policy Objective	Strategy	Key Activities	Indicators	Timelines	Responsible Agencies	Costs ($J)
effectively mitigated and managed LMOs					Scientific Panel	
		Provision of general scientific advice to competent authorities	Scientific advice provided to competent authorities	Yrs 1-5	NBC	Staff time
		Ensure risk assessments undertaken meet the standard for approval of the Scientific Panel prior to consideration	All risk assessments undertaken meet the approval of the Scientific Panel prior to consideration	Yrs 1 -5	Scientific Panel	Staff time
		Development or identification of risk management mechanisms, measures and strategies to regulate, manage or control the risks associated with the development, use, release and transboundary movement of LMOs resulting from biotechnology which are likely to have adverse environmental impacts and risks to human health and the period assessment of effectiveness and feasibility of these measures and strategies	Risk management mechanisms developed or identified and periodically evaluated	Yrs 1-3	Scientific Panel	Staff time

Policy Objective	Strategy	Key Activities	Indicators	Timelines	Responsible Agencies	Costs ($J)
		Implementation of risk management mechanisms, measures and strategies developed or identified by the Scientific Panel	Risk management mechanisms implemented	Yrs 4-5	Implementing Agencies	Staff time
	Assessment of socio-economic impact	Set parameters for the socio-economic impact assessment of an LMO	Parameters for the socio-economic impact assessment of an LMO set	Yr 2	NBC	Staff time
		Ensure that public is made aware that submissions can be made to the Competent Authorities for claims of adverse potential or actual effects of the use or introduction of an LMO	Public awareness campaign implemented	Yrs 1-5	Lead: Competent Authorities Support: IOJ	2,000,000
	Regulation of LMOs for domestic use	Make decisions on LMOs based on available scientific information and/or the findings of a risk assessment and the application of the precautionary approach	Decisions on LMOs made based on available scientific information and/or the findings of a risk assessment and the application of the precautionary approach	Yrs 1-5	Lead: Competent Authorities, NBC Support: IOJ (Jamaica BCH)	Staff time
		Development of guidelines for the handling, storage, transportation and disposal of LMOs in domestic and commercial use and for research purposes	Guidelines developed	Yrs 1-3	Lead: Competent Authority Support: NBC	3,000,000

Policy Objective	Strategy	Key Activities	Indicators	Timelines	Responsible Agencies	Costs ($J)
		Posting of all guidelines and other regulatory instruments developed for LMOs in domestic use in the BCH	Guidelines and other regulatory instruments developed for LMOs in domestic use posted in the BCH	Yrs 1-3	Lead: IOJ (Jamaica BCH) Support: Competent Authority, NBC	Staff time
	Promotion of Safe Practices (Handling, Transport, Packing and Identification)	Development of guidelines for the development and implementation of internal safety procedures for public or private organizations engaged in modern biotechnology research or the use, transportation, storage or handling of LMOs	Guidelines developed for the development and implementation of internal safety procedures for public or private organization's engaged in modern biotechnology research or the use, transportation, storage or handling of LMOs	Yrs 1-3	NBC	3,000,000
		Development and implementation of internal safety procedures by publicly funded programmes	Internal safety procedures by publicly funded programmes developed and implemented	Yrs 1-5	Lead: Tertiary institutions receiving government grants or subventions; departments and agencies under the MRE, MIIC, Ministry with responsibility for agriculture and fisheries, MOH,	Staff time

Policy Objective	Strategy	Key Activities	Indicators	Timelines	Responsible Agencies	Costs ($J)
					Ministry with responsibility for Science and Technology and any other line ministry in which personnel are directly exposed to LMOs; Customs Department, Ports of Entry; etc. Support: NBC	
	Standards for contained use, field trials and deliberate release	Development of standards for the handling of LMOs that are destined/being imported for contained use; and being developed within Jamaica	Standards for the handling of LMOs that are destined/being imported for contained use; and being developed within Jamaica developed	Yrs 1-2	Lead: Competent Authorities Support: NBC	3,000,000
		Development of protocols for the establishment and monitoring of field trials and the deliberate release of LMOs into the environment	Protocols for the establishment and monitoring of field trials and the deliberate release of LMOs into the environment developed	Yrs 1-2	Lead: Competent Authorities Support: NBC	3,000,000

Policy Objective	Strategy	Key Activities	Indicators	Timelines	Responsible Agencies	Costs ($J)
		Development of certification standards for organizations developing and/or handling LMOs	Certification standards for organizations developing and/or handling LMOs developed	Yrs 4-5	Lead: Competent Authorities Support: NBC	500,000
		Enact regulations to address standards for contained use including field trials and deliberate release of LMOs	Drafting instructions prepared to address standards for contained use including field trials and deliberate release of LMOs enacted	Yrs 4-5	Lead: MRE, MRA Support: NBC, CPC	Staff time
Promote the development and utilization of the technology (modern biotechnology) at the national level that may provide financial benefits to the relevant sectors	Institutions to Promote Development and Utilization	Train staff	Staff involved with LMOs receive training in international standards and best practices	Yrs 1-5	Lead: MRA, SRC Support: Universities	TBD
		Conduct research in GM crops directed particularly at the needs of small farmers	Research in GM crops directed particularly at the needs of small farmers conducted	Yrs 1-5	MRA, SRC, Universities, CARDI	TBD
		Exchange of scientific, technical, environmental and legal information on, and experience with, LMOs	Up to date information uploaded to the Jamaica BCH	Yrs 1-5	IOJ (Jamaica BCH)	Staff time
	Registration of Biosafety Entities and Practitioners	Institute mandatory registration, monitoring and evaluation of all	Biosafety practitioners registered	Yrs 1-5	SRC	Staff time

Policy Objective	Strategy	Key Activities	Indicators	Timelines	Responsible Agencies	Costs ($J)
		entities and practitioners involved or associated with biosafety research.				
Establish standards for the labelling of LMOs	Implementation of Labelling Standards	Development and periodic review of standards for the labelling and identification of LMOs	Standards for the labelling and identification of LMOs developed and periodically reviewed	Yrs 1-2 (development) Yrs 3-5 (review)	Lead: BSJ Support: NBC	Staff time
		Incorporation of labelling and identification standards in ongoing monitoring regimes	Labelling and identification standards included in ongoing monitoring regimes	Yrs 1-5	BSJ, NCRA, CAC, NEPA, JCA, relevant MRA departments and agencies	Staff time
		Publication of standards developed and any subsequent amendments to the BCH	Standards developed and any subsequent amendments published in the BCH	Yrs 1-5	Lead: IOJ (Jamaica BCH), BSJ	Staff time $500,000 (for publications in newspapers)
Increase public education and awareness raising on biosafety to facilitate effective implementation of the national biosafety regime	Public awareness and participation in biosafety policy implementation	Development and implementation of ongoing Public Education Programme on Biosafety	Public Education Programme on Biosafety developed and implemented	Yr 1 (development) Yrs 2-5 (implementation)	Lead: Competent Authorities Support: NBC	5,000,000

Policy Objective	Strategy	Key Activities	Indicators	Timelines	Responsible Agencies	Costs ($J)
		Promotion of the inclusion of information on modern biotechnology in public education campaigns of public and private entities involved in public awareness building issues related to science, the environment, agriculture and consumer protection and the curricula of vocational or tertiary institutions conducting training in the science, environmental or agricultural fields	Inclusion of information on modern biotechnology in public education campaigns and curricula promoted	Yrs 1-5	Lead: MRE, NEPA, NBC	2,000,000
		Provision of information on decisions in keeping with transparent decision making and Articles 10 and 12 of the Cartagena Protocol and with the Access to Information Act	Information made available to the public	Yrs 1-5	Lead: NBC Support: Competent Authorities, MRE, BCH	This output will be included in the 5,000,000 above for the public education programme
Increase the capacity of the relevant national institutions to implement and monitor a national framework for biosafety	Capacity Building	Inclusion of strategies to implement the Biosafety Policy in annual plans and programmes of relevant MDAs	Strategies to implement the Biosafety Policy included in annual plans and programmes of relevant MDAs	Yrs 1-5	Competent Authorities	Staff time

Policy Objective	Strategy	Key Activities	Indicators	Timelines	Responsible Agencies	Costs ($J)
		Identification and maximization of opportunities for the strengthening of the capacities of the NBC and the Competent Authorities	Opportunities for the strengthening of the capacities of the NBC and the Competent Authorities identified and maximized	Yrs 1-5	Lead: Ministries responsible for competent authorities Support: PIOJ	Staff time
		Increasing capacity for the testing of plants, animals and their products	Capacity increased for the testing of plants, animals and their products	Yrs 1-5	Lead: Competent Authorities, Ministry with responsibility For Agriculture And Fisheries, JCA	TBD
		Establishment of a Biosafety Registry	Database established and maintained	Yrs 1-5	NEPA (Biosafety Registrar)	Staff time
		Develop Resource Mobilization Plan	Funding identified/obtained for the implementation of the Policy	Yrs 1-5	Lead: MRE Support: Ministries responsible for competent authorities, NBC	Staff time
		Develop Capacity Building Action Plan	Plan developed to train scientists, phytosanitary officers, customs officers, inspectors and others on LMO monitoring, enforcement and	Yr 1-2	Lead: CNAs and other implementing MDAs Support: NBC	Staff time

Policy Objective	Strategy	Key Activities	Indicators	Timelines	Responsible Agencies	Costs ($J)
			emergency response measures			
		Training in LMO detection and analysis provided	Key personnel trained (see above)	Yrs 1-5	CNAs and other implementing MDAs	Staff time; costs TBD
		Upgrade laboratories for the detection and analysis of LMOs	Number of laboratories upgraded	Yrs 1-5	CNAs	Staff time; costs TBD

4.4 *Monitoring and Evaluation Framework*

GOAL	SUMMARY/Objectives	INDICATORS	MEANS OF VERIFICATION	ASSUMPTIONS
To provide a safe enabling environment of the development, transboundary movement, handling and use of living modified organisms, while managing risks to human health, agriculture and biodiversity	**1. Ensure the effective regulation of the transboundary movement (import and export) of LMOs is in keeping with the relevant international rules and standards as well as the tenets of the Cartagena Protocol on Biosafety**			
Outcomes	Effective regulation of the transboundary movement (import and export) of LMOs is in keeping with the relevant international rules and standards as well as the tenets of the Cartagena Protocol on Biosafety			
Outputs	Fully functional National Biosafety Committee	Successful completion of activities undertaken from the implementation plan assigned to the NBC	Minutes of NBC meetings Guidelines and standards reviewed and/or developed	Committee members are able to meet and carry out the work required
Activities	Establishment of the NBC	NBC is established	Minutes of NBC meetings # of agencies represented at meetings	MDAs and other organizations nominate staff to be

GOAL	SUMMARY/Objectives	INDICATORS	MEANS OF VERIFICATION	ASSUMPTIONS
				a part of the committee
	Development and implementation of regulatory framework	Legislation is published in the Gazette	Jamaica Gazette	Stakeholders agree with draft legislation proposed
	Monitoring of sharing of decisions and notifications with the BCH	# of decisions and notifications shared by the BCH	BCH Records	Staff available at the IOJ to update the BCH
	Ensure that the possible adverse effects of LMOS on human health and biodiversity are effectively mitigated and managed	# of reports received from MOH	Files of competent authorities and NBC	Funding and personnel available
Outcomes	The possible adverse effects of LMOS on human health and biodiversity are effectively mitigated and managed	# of reports received from MOH	Files of competent authorities and NBC	Funding and personnel available
Outputs	Scientific advice provided to competent authorities	# of reports from the NBC	Files of competent authorities and NBC	NBC and Scientific Panel fully functional
	Risk assessment procedures for import/export, use, handling, research and development of LMOs	Risk assessment procedures prepared	Consultant report	Funding available to hire consultant Suitable persons respond to RFP
	Risk management mechanisms, measures and strategies	Risk management mechanisms, measures and strategies identified	Consultant report	Funding available to hire consultant Suitable persons respond to RFP

GOAL	SUMMARY/Objectives	INDICATORS	MEANS OF VERIFICATION	ASSUMPTIONS
	Parameters for socio-economic impact assessments of LMOs	Parameters for socio-economic impact assessments of LMOs identified	Reports from NBC	NBC is fully functional
	Guidelines for the handling, storage, transportation and disposal of LMOs in domestic and commercial use and for research purposes	Approved guidelines	Documentation from the relevant competent authorities	Staff available at the CNAs
	Internal safety procedures for public or private organizations engaged in modern biotechnology research or the use, transportation, storage or handling of LMOs	Approved procedures	Documentation from the relevant organizations	Organizations are advised that these procedures must be developed and personnel available to document the procedures
	Implementation of internal safety procedures by publicly funded programmes	Internal safety procedures implemented by publicly funded programmes	Annual reports	Monitoring/audit mechanism in place at these facilities to ensure that procedures are implemented
	Standards for the handling of LMOs that are destined/being imported for contained use; and being developed within Jamaica	Standards published in the Gazette	Jamaica Gazette	Requisite information sent to the Jamaica Printing Service for publication in the Gazette

GOAL	SUMMARY/Objectives	INDICATORS	MEANS OF VERIFICATION	ASSUMPTIONS
	Protocols for the establishment and monitoring of field trials and the deliberate release of LMOs into the environment	Protocols established	Documentation from the Ministry with responsibility for agriculture and fisheries	Personnel available to develop protocols
	Certification standards for organizations developing and/or handling LMOs	Certification standards published by the BSJ	Standard documents	Funding and personnel available
	Legislation to address standards for contained use including field trials and deliberate release of LMOs	Legislation published in the Jamaica Gazette	Jamaica Gazette	Requisite information sent to the Jamaica Printing Service for publication in the Gazette
Activities	Development and updating of risk assessment procedures for import/export, use, handling, research and development of LMOs	Risk assessment procedures developed and updated	Documentation from the NBC and competent authorities	NBC is fully functional
	Development and implementation of Guidelines for the handling, storage, transportation and disposal of LMOs in domestic and commercial use and for research purposes	Guidelines developed and implemented	Consultant report Documentation from the NBC and competent authorities	Funding available to hire consultant Suitable persons respond to RFP

GOAL	SUMMARY/Objectives	INDICATORS	MEANS OF VERIFICATION	ASSUMPTIONS
	Development of guidelines for the development and implementation of internal safety procedures for public or private organizations engaged in modern biotechnology research or the use, transportation, storage or handling of LMOs	Guidelines developed and implemented	Consultant report Documentation from the NBC and competent authorities	Funding available to hire consultant Suitable persons respond to RFP
	Development and implementation of internal safety procedures by publicly funded programmes	Safety procedures developed and implemented	Procedures document	Organizations are advised that these procedures must be developed and personnel available to document the procedures
	Development of standards for the handling of LMOs that are destined/being imported for contained use; and being developed within Jamaica	Standards developed	Standards document	Funding and personnel available
	Development of protocols for the establishment and monitoring of field trials and the deliberate release of LMOs into the environment	Protocols developed	Protocol documents	Funding and personnel available

GOAL	SUMMARY/Objectives	INDICATORS	MEANS OF VERIFICATION	ASSUMPTIONS
	Development of certification standards for organizations developing and/or handling LMOs	Certification standards developed	Standards document	Funding and personnel available
	Enact legislation to address standards for contained use including field trials and deliberate release of LMOs	Legislation published in Jamaica Gazette	Jamaica gazette	Requisite information sent to the Jamaica Printing Service for publication in the Gazette
	Promote the development and utilization of the technology (modern biotechnology) at the national level that may provide financial benefits to the relevant sectors			
Outcomes	Promotion of the development and utilization of the technology (modern biotechnology) at the national level that may provide financial benefits to the relevant sectors			
Outputs	Trained staff	# of staff trained	Attendance registers Training session reports	Funding available for training
	Research in GM crops directed particularly at the needs of small farmers	Research conducted	Research reports	Funding and personnel available

GOAL	SUMMARY/Objectives	INDICATORS	MEANS OF VERIFICATION	ASSUMPTIONS
	Exchange of scientific, technical, environmental and legal information on, and experience with, LMOs	Information posted in the BCH	BCH records	Personnel available at the IOJ to update the BCH
	Registration, monitoring and evaluation of all entities and practitioners involved or associated with biosafety research	# of entities and practitioners registered	Biosafety Registry	Funding and personnel available
Activities	Train staff	# of staff trained	Attendance registers Training session reports	Funding available for training
	Conduct research in GM crops directed particularly at the needs of small farmers	Research conducted	Research reports	Funding and personnel available
	Exchange of scientific, technical, environmental and legal information on, and experience with, LMOs through the BCH	Information posted in the BCH	BCH records	Personnel available at the IOJ to update the BCH
	Institute mandatory registration, monitoring and evaluation of all entities and practitioners involved or associated with biosafety research.	Information posted in the BCH	BCH records	Personnel available
	Establish standards for the labelling of LMOs			

GOAL	SUMMARY/Objectives	INDICATORS	MEANS OF VERIFICATION	ASSUMPTIONS
Outcomes	Labelling standards established for LMOs	Labelling standards established	Standards document	Funding and personnel available
Outputs	Standards for the labelling and identification of LMOs	Identification of LMOs	List of LMOs	Personnel available
	Labelling and identification standards incorporated in ongoing monitoring regimes	# of monitoring programmes including labelling and identification standards	Monitoring reports	Personnel aware of the requirements and activities incorporated in relevant operational and individual work plans
Activities	Development and periodic review of standards for the labelling and identification of LMOs	Standards developed Yearly review of standards	Standard document Reports on the review of the standards	Funding and personnel available
	Incorporation of labelling and identification standards in ongoing monitoring regimes	# of monitoring programmes including labelling and identification standards	Monitoring reports	Personnel aware of the requirements and activities incorporated in relevant operational and individual work plans
	Publication of standards developed and any subsequent amendments to the BCH	Standards published	BCH records	Personnel available at the IOJ to update the BCH

GOAL	SUMMARY/Objectives	INDICATORS	MEANS OF VERIFICATION	ASSUMPTIONS
	Increase public education and awareness raising on biosafety to facilitate effective implementation of the national biosafety regime			
Outcomes	Increased public awareness on biosafety to facilitate effective implementation of the national biosafety regime	KAPB study before and after implementation of the plan	KAPB reports	Funding and personnel available to carry out studies
Outputs	Public Education Programme on Biosafety	# of public education activities # of public education material developed	Reports of public education activities Public education materials	Funding and personnel available to carry our activities
	Inclusion of information on modern biotechnology in public education campaigns of public and private entities involved in public awareness building issues related to science, the environment, agriculture and consumer protection and the curricula of vocational or tertiary institutions conducting training in the science, environmental or agricultural fields	# of curricula including biosafety # of education campaigns including biosafety	Curricula Education campaign materials	Funding and personnel available to carry our activities

GOAL	SUMMARY/Objectives	INDICATORS	MEANS OF VERIFICATION	ASSUMPTIONS
Activities	Development and implementation of ongoing Public Education Programme on Biosafety	# of public education activities implemented # of public education material developed	Reports of public education activities Public education materials	Funding and personnel available to carry our activities
	Promotion of the inclusion of information on modern biotechnology in public education campaigns of public and private entities involved in public awareness building issues related to science, the environment, agriculture and consumer protection and the curricula of vocational or tertiary institutions conducting training in the science, environmental or agricultural fields	# of curricula including biosafety # of education campaigns including biosafety	Curricula Education campaign materials	Funding and personnel available to carry our activities
	Increase the capacity of the relevant national institutions to implement and monitor a national framework for biosafety			
Outcomes	Increased capacity of the relevant national institutions to implement and monitor a national framework for biosafety	# of persons trained Upgrading of laboratories	Attendance registers Training session reports Reports on upgrades to laboratories	Funding and personnel available

GOAL	SUMMARY/Objectives	INDICATORS	MEANS OF VERIFICATION	ASSUMPTIONS
Outputs	Strategies to implement the Biosafety Policy included in annual plans and programmes of relevant MDAs	# of annual plans and programmes including implementation of Biosafety Policy	Annual plans and programmes	Representatives from MDAs who are members of the NBC, with the support of the NBC and the National Focal Point, make representation to Executive Management to ensure that these matters are included in annual plans and programmes
	Capacity increased for the testing of plants, animals and their products	# of laboratories upgraded	Reports on upgrades to laboratories Certification of labs	Funding available
Activities	Inclusion of strategies to implement the Biosafety Policy in annual plans and programmes of relevant MDAs	# of annual plans and programmes including implementation of Biosafety Policy	Annual plans and programmes	Representatives from MDAs who are members of the NBC, with the support of the NBC and the National Focal Point, make representation to Executive Management to ensure that these matters are included in annual plans and programmes

GOAL	SUMMARY/Objectives	INDICATORS	MEANS OF VERIFICATION	ASSUMPTIONS
	Upgrade facilities for the testing of plants, animals and their products by the Ministry with responsibility for agriculture and fisheries and Jamaica Customs Agency	# of laboratories upgraded	Reports on upgrades to laboratories Certification of labs	Funding available

Appendix I: Policies and Laws which directly or indirectly apply to LMOs[14]

Title	Status	Main Provisions	Responsible Institution
Policy on Science and Technology, 1990	Being revised (draft Science, Technology and Innovation Policy)	Recognizes biotechnology as a priority area, particularly for agricultural, crop and animal production as well as research and development activities. It recognizes the need to manage the use of the island's biological resources and to build additional capacity in biotechnology.	National Commission on Science and Technology
Biotechnology Policy for Economic and Social Development	Draft 2006	Focuses exclusively on biotechnology, including research and development activities	National Commission on Science and Technology
Food Safety Policy	In effect	To implement programmes which promote high standards of food hygiene and maintain systems of surveillance and control to ensure compliance with those standards.	Ministry of Agriculture and Fisheries and the Ministry of Health
National Plant Health Policy	In effect	Maximisation of Jamaica's food production and trade; protection of the environment from invasive plant pests; and increasing public awareness about the importance of plant health development of an efficient plant health system.	Ministry of Agriculture and Fisheries
National Organic Agriculture Policy	Draft	To create a framework for the development of organic agriculture in Jamaica. It will focus on regulation, certification and monitoring of	Ministry of Agriculture and Fisheries

[14] Status as at January 2018

Title	Status	Main Provisions	Responsible Institution
		farms, products and inputs to ensure that the sub-sector is operating at acceptable levels and can compete with international standards	
Food and Nutrition Security Policy	In effect	To create a framework for the development of organic agriculture in Jamaica. It focuses on regulation, certification and monitoring of farms, products and inputs to ensure that the sub-sector is operating at acceptable levels and can compete with international standards.	Ministry of Agriculture and Fisheries/ Ministry of Health
National Animal Health and Welfare Policy for Jamaica	Draft	To safeguard and improve the health and quality of commercially produced animals and animal products. The policy will target animal growers, producers, importers, exporters and consumers of animal products.	Ministry of Agriculture and Fisheries
Seed policy	Draft	The goal of the policy is to establish a sustainable seed system that ensures a consistent and reliable supply of clean, affordable and accessible seed in support of agriculture production, productivity, food security and biodiversity.	Ministry of Agriculture and Fisheries
Foreign Trade Policy and Action Plan	In effect	The overall aim of the policy is to increase exports in goods and services while managing the flow of imports in such a way	Ministry of Foreign Affairs and Foreign Trade

Title	Status	Main Provisions	Responsible Institution
		that the economy benefits in a sustainable manner.	
Vision 2030 Agriculture Sector Plan	In effect	To improve productivity and production in the agricultural sector using new technologies, including biotechnology, in areas such as crop development and disease control and crop/land yield.	Ministry of Agriculture and Fisheries
The Plants (Quarantine) Act, 1994	In effect	Regulates the importation of plant species and establishes controls on plant pests. In addition to quarantine procedures, the Act empowers the Minister to prohibit the importation of any plant, article or thing from any country, where he is satisfied that plant pests may be introduced into the island. This would apply to any GMO that can be classified as a 'plant pest'.	Plant Quarantine/Produce Inspection Branch, Ministry of Agriculture and Fisheries
Plants (Importation) Control Regulations, 1997 (under the Plants Quarantine Act) amended 2005	In effect	This is currently the only legal instrument that directly addresses the issue of biosafety. The regulations were enacted in 1997 and amended in 2005. Under these regulations the National Biosafety Committee is legislated to monitor the importation of any plant, seed, cutting or slip, which has been genetically modified and imported into Jamaica for the purpose of experimentation.	Plant Quarantine/Produce Inspection Branch, Ministry of Agriculture and Fisheries
Animals (Diseases and Importation) Act, 1948	In effect	Subjects imported animals, birds, reptiles and insects to a quarantine procedure.	Veterinary Services Division, Ministry of Agriculture and Fisheries

Title	Status	Main Provisions	Responsible Institution
Natural Resources Conservation Authority (NRCA) Act, 1991	In effect	Manage the physical environment of Jamaica so as to ensure the conservation, protection and proper use of its natural resources. The scope of its statutory mandate is sufficiently broad to address various biosafety issues and the possible impact of LMOs on human health and biodiversity.	Natural Resources Conservation Authority, National Environment and Planning Agency
Natural Resources Conservation (Permits and Licences) Regulations, 1996 (amended 2015)	In effect	Introduction of species of flora, fauna and genetic material and the introduction of living modified organisms.	Natural Resources Conservation Authority, National Environment and Planning Agency
Consumer Protection Act 2005 (Amended 2012)	In effect	Keeps proper records of all consumer complaints, all actions taken in relation to such complaints and results of those actions and covers breaches resulting in detriment to consumers.	Consumer Affairs Commission
Patent Act, 1857	In effect	Sets out procedures for the granting of patents.	Jamaica Intellectual Property Office
Dangerous Drugs Act, 1948	In effect	Regulates the importation, exportation, manufacture, sale and use of dangerous drugs.	Ministry of Health
Scientific Research Council Act, 1960	In effect	Establishes a Council for which the duty, *inter alia,* is to undertake and foster scientific research in Jamaica and to encourage the application of the results of this research to the exploitation and development of the resources of the island.	Scientific Research Council

Title	Status	Main Provisions	Responsible Institution
Customs Act, 1941	In effect	Protection of the borders of Jamaica including protection from all goods or products deemed harmful to the nation. This includes agricultural products.	Jamaica Customs Agency
Food and Drugs Act, 1975	In effect	Importation, sale, labelling, packaging and advertising of food and drug products.	Ministry of Health
Pharmacy Act, 1975	In effect	The importation or sale of LMOs in the form of pharmaceutical products may be restricted.	Ministry of Health
The Pesticides Act, 1975	In effect	Importation, manufactures, sale, labelling and use of pesticides, and may thus affect LMOs being utilized for pest control purposes.	Ministry of Health

Appendix II: Information Required Concerning Living Modified Organisms Intended for Direct use as Food or Feed, or for Processing[15]

a) The name and contact details of the applicant for a decision for domestic use.
b) The name and contact details of the authority responsible for the decision.
c) Name and identity of the living modified organism.
d) Description of the gene modification, the technique used, and the resulting characteristics of the living modified organism.
e) Any unique identification of the living modified organism.
f) Taxonomic status, common name, point of collection or acquisition, and characteristics of recipient organism or parental organisms related to biosafety.
g) Centres of origin and centres of genetic diversity, if known, of the recipient organism and/or the parental organisms and a description of the habitats where the organisms may persist or proliferate.
h) Taxonomic status, common name, point of collection or acquisition, and characteristics of the donor organism or organisms related to biosafety.
i) Approved uses of the living modified organism.
j) A risk assessment report consistent with Annex III.
k) Suggested methods for the safe handling, storage, transport and use, including packaging, labelling, documentation, disposal and contingency procedures, where appropriate.

[15] Adopted from Annex II of the Cartagena Protocol

Appendix III: Risk Assessment[16]

Objective

The objective of risk assessment, under this Policy, is to identify and evaluate the potential adverse effects of living modified organisms on the conservation and sustainable use of biological diversity in the likely potential receiving environment, taking also into account risks to human health.

Use of risk assessment

Risk assessment is, inter alia, used by competent authorities to make informed decisions regarding living modified organisms.

General principles

1. Risk assessment should be carried out in a scientifically sound and transparent manner, and can take into account expert advice of, and guidelines developed by, relevant international organizations.

2. Lack of scientific knowledge or scientific consensus should not necessarily be interpreted as indicating a particular level of risk, an absence of risk, or an acceptable risk.

3. Risks associated with living modified organisms or products thereof, namely, processed materials that are of living modified organism origin, containing detectable novel combinations of replicable genetic material obtained through the use of modern biotechnology, should be considered in the context of the risks posed by the non-modified recipients or parental organisms in the likely potential receiving environment.

4. Risk assessment should be carried out on a case-by-case basis. The required information may vary in nature and level of detail from case to case, depending on the living modified organism concerned, its intended use and the likely potential receiving environment.

Methodology

The process of risk assessment may on the one hand give rise to a need for further information about specific subjects, which may be identified and requested during the assessment process, while on the other hand information on other subjects may not be relevant in some instances.

To fulfil its objective, risk assessment entails, as appropriate, the following steps:

[16] Adopted from Annex III of the Cartagena Protocol

a) An identification of any novel genotypic and phenotypic characteristics associated with the living modified organism that may have adverse effects on biological diversity in the likely potential receiving environment, taking also into account risks to human health;
b) An evaluation of the likelihood of these adverse effects being realized, taking into account the level and kind of exposure of the likely potential receiving environment to the living modified organism;
c) An evaluation of the consequences should these adverse effects be realized;
d) An estimation of the overall risk posed by the living modified organism based on the evaluation of the likelihood and consequences of the identified adverse effects being realized;
e) A recommendation as to whether or not the risks are acceptable or manageable, including, where necessary, identification of strategies to manage these risks; and
f) Where there is uncertainty regarding the level of risk, it may be addressed by requesting further information on the specific issues of concern or by implementing appropriate risk management strategies and/or monitoring the living modified organism in the receiving environment.

Points to consider

Depending on the case, risk assessment takes into account the relevant technical and scientific details regarding the characteristics of the following subjects:

(a)Recipient organism or parental organisms. The biological characteristics of the recipient organism or parental organisms, including information on taxonomic status, common name, origin, centres of origin and centres of genetic diversity, if known, and a description of the habitat where the organisms may persist or proliferate;

(b)Donor organism or organisms. Taxonomic status and common name, source, and the relevant biological characteristics of the donor organisms;

(c)Vector. Characteristics of the vector, including its identity, if any, and its source or origin, and its host range;

(d)Insert or inserts and/or characteristics of modification. Genetic characteristics of the inserted nucleic acid and the function it specifies, and/or characteristics of the modification introduced;

(e)Living modified organism. Identity of the living modified organism, and the differences between the biological characteristics of the living modified organism and those of the recipient organism or parental organisms;

(f)Detection and identification of the living modified organism. Suggested detection and identification methods and their specificity, sensitivity and reliability;

(g)Information relating to the intended use. Information relating to the intended use of the living modified organism, including new or changed use compared to the recipient organism or parental organisms; and

(h)Receiving environment. Information on the location, geographical, climatic and ecological characteristics, including relevant information on biological diversity and centres of origin of the likely potential receiving environment.

Appendix IV: Participants in Consultation Sessions on draft Biosafety Policy (Green Paper)

The general public was invited to comment on the draft Biosafety Policy for Jamaica (Green Paper) through print advertisements placed in the major newspapers, as well as on the MRE's social media sites. In addition, two virtual consultation sessions were convened on 14 and 15 October 2021 at which the Green Paper was presented, and comments invited.

The following entities participated in the consultation sessions:

1	All Natural Caribbean Spice
2	Attorney-General's Chambers
3	Bureau of Standards Jamaica
4	Campari
5	Cannabis Licensing Authority
6	Caribbean Broilers
7	College of Agriculture, Science and Education
8	Consumer Affairs Commission
9	Federated Pharmaceutical
10	Forestry Department
11	Institute of Jamaica
12	Jah-Jireh Herbal Limited
13	Jamaica Customs Agency
14	Jamaica Environmental Entrepreneurs Advocacy Network
15	Jamaica Flour Mills
16	Jamaica Institute of Environmental Professionals (JIEP)
17	Jamaica National Agency for Accreditation (JANAAC)
18	JIO H2K
19	Ministry of Agriculture & Fisheries • Research and Development Division; • Plant Quarantine/Produce Inspection Branch; • Veterinary Services Division
20	Ministry of Economic Growth and Job Creation
21	Ministry of Foreign Affairs and Foreign Trade
22	Ministry of Health and Wellness
23	Ministry of Housing, Urban Renewal, Environment and Climate Change
24	Musson
25	National Commission on Science and Technology

26	National Compliance and Regulatory Authority (NCRA)
27	National Environment and Planning Agency/Scientific Authority
28	P.A. Benjamin Manufacturing Company Limited
29	Rural Agriculture Development Authority (RADA)
30	Scientific Research Council
31	Seprod Group
32	T Geddes Grant
33	The Caribbean Community (CARICOM) Secretariat

Glossary

Advance informed agreement (AIA)
The AIA procedure applies to the first intentional transboundary movement of LMOs for intentional introduction into the environment of the Party of import. It includes four components: notification by the Party of export or the exporter, acknowledgment of receipt of notification by the Party of import, decision procedure and review of decisions. The purpose of this procedure is to ensure that importing countries have both the opportunity and the capacity to assess risks that may be associated with the LMO before agreeing to its import.

Biodiversity
"Biological diversity" is "the variability among living organisms from all sources, including, 'inter alia', terrestrial, marine, and other aquatic ecosystems, and the ecological complexes of which they are part: this includes diversity within species, between species and of ecosystems." (Convention on Biological Diversity)

Biosafety
This is a term used to describe efforts to reduce and eliminate the potential risks resulting from biotechnology and its products. For the purposes of the Biosafety Protocol, this is based on the precautionary approach, whereby the lack of full scientific certainty should not be used as an excuse to postpone action when there is a threat of serious or irreversible damage.[17]

Biosafety Clearing-House
The Biosafety Clearing-House is a mechanism set up by the Cartagena Protocol on Biosafety to facilitate the exchange of information on Living Modified Organisms (LMOs) and assist the Parties to better comply with their obligations under the Protocol. Global access to a variety of scientific, technical, environmental, legal and capacity building information is provided in the six official languages of the United Nations.

Biotechnology
Technological applications that use biological systems and living organisms to make or modify products for human use; a variety of techniques that involve the use and manipulation of living organisms to make commercial products. These techniques include cell culture, tissue culture, embryo transfer, and recombinant DNA technology (genetic engineering).

Biotechnology is currently applied in the health sector (for e.g. antibiotics, insulin, interferon…), in the agri-food system (micro-organisms, plants and animals), and in industrial

[17] http://bch.cbd.int/protocol/

processes such as waste recycling. Biotechnology and genetic engineering are often used interchangeably.

Contained use
Any operation, undertaken within a facility, installation or other physical structure, which involves LMOs that are controlled by specific measures that effectively limit their contact with, and their impact on, the external environment.

Cross breeding
Use of techniques involving crossing plants to produce varieties with particular characteristics (traits) which are carried in the genes of the plants and passed on to future generations. Conventional/traditional plant breeding refers to techniques others than modern biotechnology, in particular cross-breeding, back-crossing.

Domestic Use
Any operation undertaken at the national level, whether at a facility, installation or physical structure or within the household, which involves LMOs.

DNA
The molecule that encodes genetic information in the cells that determines an organism's physical traits. DNA constitutes the building blocks from which genes are constructed. Every inherited characteristic has its origin somewhere in the code of the organism's complement of DNA.

Genetic Engineering
The selective, deliberate alteration of genes (genetic material) by man. This term has come to have a very broad meaning including the manipulation and alteration of the genetic material (constitution) of an organism in such a way as to allow it to produce endogenous proteins with properties different from those of the traditional (historic/typical), or to produce entirely different (foreign) proteins altogether. Some other words often applicable to the same process are gene splicing, gene manipulation, or recombinant DNA technology.

Genetic Modification
Molecular-level techniques used to move genetic material from the cells of one organism to those of another. These techniques, which may be used to transfer genes between unrelated organisms or to remove and rearrange genes within a species, are also called genetic engineering, gene splicing or transgenic.

Genetically Modified Organism or "GMO"
Any living organism that possesses a novel combination of genetic material obtained through the use of modern biotechnology.

In-vitro
Refers to processes outside the living organism.
In-vitro means literally "in glass" (from Latin: vitrum=glass). In *in vitro* experiments, organisms and structures are investigated under experimental conditions rather than in their natural context. For instance, if a plant is grown on a culture medium in a Petri dish and brought to flower there, then the plant is said to be flowering in vitro.
The term has become familiar in connection with artificial fertilization of egg cells in test tubes (*in vitro* fertilization).
By contrast, *in vivo* (Latin: vivum=life) means that a process takes place in the living organism or under natural conditions.

Living Modified Organism (LMO)
Any living organism that possesses a novel combination of genetic material obtained through modern biotechnology. A living organism is a biological entity capable of transferring or replicating genetic material.

Modern biotechnology
The application of in vitro nucleic acid techniques or the fusion of cells beyond the taxonomic family or other biotechnology techniques that overcome natural physiological, reproductive or recombination barriers and that are not techniques used in traditional breeding and selection.

Precautionary approach
One of the outcomes of the United Nations Conference on Environment and Development (also known as the Earth Summit) held in Rio de Janeiro, Brazil, in June 1992, was the adoption of the Rio Declaration on Environment and Development, which contains 27 principles to underpin sustainable development. One of these principles is Principle 15 which states that "In order to protect the environment, the precautionary approach shall be widely applied by States according to their capabilities. Where there are threats of serious or irreversible damage, lack of full scientific certainty shall not be used as a reason for postponing cost-effective measures to prevent environmental degradation."

The precautionary approach is reflected in a number of the provisions of the Protocol, such as the preamble, reaffirming "the precautionary approach contained in Principle 15 of the Rio Declaration on environment and Development "; Annex III on risk assessment which state:

"Lack of scientific knowledge or scientific consensus should not necessarily be interpreted as indicating a particular level of risk, an absence of risk, or an acceptable risk."

Release

Any intentional introduction into the environment of an LMO or a combination of LMOs without provision for containment, such as physical barriers or a combination of physical barriers together with chemical and/or biological barriers used to limit their contact with the general population and the environment.

Risk Assessment

It is based on information provided in accordance with Article 8 of the Cartagena Protocol on Biosafety and other available scientific evidence in order to identify and evaluate the possible adverse effects of LMOs (living modified organisms) on the conservation and sustainable use of biological diversity, taking also into account risks to human health.

Risk Management

The established mechanisms, measures and strategies to regulate, management and control risks identified in the risk assessment provisions of the Cartagena Protocol on Biosafety associated with the use, handling and transboundary movement of LMOs (living modified organisms).

Transboundary movement

Any movement of from an area under the jurisdiction of one State to or through an area:
(a) under the jurisdiction of another State; or
(b) not under the jurisdiction of any State, provided that at least two States are involved in the movement.

Transit

The continuous passage through an area under the jurisdiction of a State without regard to any temporary storage incidental to transport.